REVIEW

Assessing Previous Strategies and Presenting a Novel Smart Glasses to Enhance Adherence to Amblyopia Therapy in Children

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Abstract: Amblyopia treatment in children, often involving patching or atropine, faces significant challenges with adherence. Adherence to patching is often poor due to discomfort and psychosocial factors such as social stigma, while adherence data for atropine treatment remains scarce, hindering a clear understanding of patients' adherence in real-world settings. This review assesses both traditional methods and alternative strategies aimed at improving adherence, including Bangerter filters, binocular therapies, intermittent occlusion, and perceptual learning. While these alternatives help reduce the treatment burden, they do not consistently outperform conventional methods in improving visual outcomes and still face notable adherence challenges, especially in older children. Educational interventions, such as cartoons and motivational tools, show promise in improving adherence, especially in low-adherence populations, but their long-term effectiveness has yet to be established. Digital therapies such as Luminopia and CureSight represent promising alternatives to traditional amblyopia treatments, with preliminary evidence indicating improvements in visual outcomes and adherence. Nevertheless, further research is necessary to determine their efficacy and how they compare to established methods. Building on this, we hypothesize that the AmblySmart glasses, a novel technology that integrates with smart devices, could further improve adherence by linking treatment to children's screen time. However, further studies are needed to investigate this technology's effectiveness and practicality compared to traditional methods. Overall, this review highlights the importance of developing innovative approaches to optimize adherence and improve treatment outcomes in amblyopic children.

Introduction

Unilateral amblyopia is one of the most common causes of vision impairment among children with an estimated prevalence of 1-4%,^{1,2} characterized by one eye functioning with less visual efficiency compared to the other, without the presence of an organic cause, or in a manner disproportionate to any existing organic defect in the eye.³ Worldwide, the most commonly reported treatments for unilateral amblyopia are occlusion with an adhesive eye patch or penalization with atropine eye drops.³ Both treatments force the individual to use the amblyopic eye to ensure that it receives input that will support the recovery of visual function. Although patching and atropine are effective at improving visual acuity of the amblyopic eye, some children are left with residual decreased visual acuity and/or do not respond to the treatment.^{4–8}

One potential explanation for residual amblyopia is less than adequate patient adherence to the treatment.^{9–12} Occlusion dose monitors (ODMs) were the first tools to enable objective measurement of adherence in amblyopia therapy and have played a key role in understanding the dose-response relationship.¹³ Occlusion dose monitors studies for patching have shown that the actual occlusion dose received is usually not the prescribed dose.^{14–16} Using ODMs, several studies have shown that adherence to patching ranges from 40% to 57%.^{14,15,17,18} A positive linear relationship between the total dose received and visual outcome over the first 400 hours was reported. It was also recommended that to achieve a satisfactory outcome, 150–250 hours of occlusion must be applied. Moreover, Awan et al used occlusion

dose monitors to investigate the dose-response relationship in occlusion treatment. Their findings demonstrated that participants who patched for more than 3-hours had better visual outcomes than participants that patched for less than 3-hours.¹⁵

However, ODMs relatively large size and bulk have limited their feasibility for routine clinical use or large-scale implementation.¹⁴ More recently, the development of microsensors such as TheraMon has improved practicality by allowing discreet attachment to eye patches or spectacle temples, making adherence monitoring more scalable.¹⁹ Expanding upon this concept, the AmblySmart innovation incorporates the TheraMon skin-contact sensing method into a fully electronic and intelligent system, enabling real-time adherence tracking with minimal effort from parents or clinicians; its design and application are explored in detail later in this manuscript.

Poor adherence to amblyopia treatment may be correlated to the nature of the treatment itself,²⁰ the characteristics of the child being treated,²¹ or both. The leading causes of poor adherence for adhesive patching are discomfort and social issues.^{10,20} Some of the factors that were associated with poor adherence were related to the adhesive patch. For example, skin irritation, cosmetic issues, and continuous occlusion of the non-amblyopic eye were significantly associated with poor adherence to patching.^{11,21} It was suggested that younger children have higher adherence than older children.¹⁸ Other factors that are not related to the treatment itself were also found to be associated with poor adherence. For instance, poor parental fluency in the national language, parents' level of education, and severity of amblyopia were significant predictors for poor adherence.¹⁸ Furthermore, psychosocial factors such as social stigma and lower social acceptance were also found to be significantly associated with poor adherence to patching.^{11,21}

Researchers have explored various alternative and supplementary treatments to address the adherence challenges associated with traditional adhesive patching. With the growing presence of wearable digital devices in everyday life, technology is increasingly being used to make paediatric treatments more engaging and accessible.²² In amblyopia treatment, several recent approaches have incorporated digital platforms to improve adherence and outcomes. For example, Luminopia delivers therapeutic video content through a headset to stimulate the amblyopic eye,²³ while CureSight uses eye-tracking to adjust visual input and monitor adherence remotely.²⁴ These innovations reflect a broader shift toward integrating technology into treatment, though more research is needed to confirm their effective-ness compared to traditional methods. This review provides a comprehensive evaluation of traditional and emerging amblyopia treatments, emphasizing their impact on both adherence and treatment effectiveness, and introduces a novel smart glasses innovation designed to align therapy with children's daily routines to improve both outcomes.

Method of Literature Search

To compile the evidence necessary for this review on the most common alternative treatments and strategies to overcome adherence issue with the adhesive patching, a comprehensive and systematic literature search was conducted. Multiple electronic databases, including PubMed, Scopus, and Web of Science, to ensure a broad and inclusive collection of relevant studies were utilized. The search strategy was designed to capture both the breadth and depth of the topic, incorporating a combination of keywords and MeSH terms related to "amblyopia treatment", "compliance", "adherence", "compliance with patching treatment", "compliance with atropine treatment", "compliance with amblyopia treatment", "alternative amblyopia treatment", and "amblyopia in children". The search was refined by mainly focusing on studies published in the English language from 2000 to 2024, to ensure the relevance and timeliness of the evidence.

Alternative Treatments to Overcome Adherence Issues Associated with Patching

Atropine Eye Drops

Atropine penalization is the most common alternative treatment for amblyopia when children do not adhere to patching treatment.¹⁰ Atropine sulfate 1% is an anticholinergic agent that blocks acetylcholine to temporarily dilate the pupil and paralyze the ciliary muscles. As a result, when the patient is wearing distance correction, the near vision is intentionally blurred in the non-amblyopic eye thus forcing the patient to use the amblyopic eye for near tasks.²⁵

Over the past two decades, atropine has been extensively studied as a treatment for amblyopia. A 2002 randomized clinical trial comparing patching and atropine for moderate amblyopia found that while patching initially led to faster improvements, the final visual acuity gains were similar for both treatments.²⁶ In 2004, a trial comparing daily and weekend atropine in children aged 3 to 7 years with moderate amblyopia found no significant difference in visual acuity improvement between the two regimens.²⁷ Initially, atropine was thought to be ineffective for severe amblyopia because it might not sufficiently blur the fellow eye. However, the Pediatric Eye Disease Investigator Group challenged this belief with two trials. The first trial, involving children aged 3 to 6 years, showed that weekend atropine with a Plano lens resulted in a visual acuity improvement of 5.1 logMAR lines, similar to the improvement seen with spectacle correction.²⁸ The second trial, in children aged 7 to 12 years, found that weekend atropine was nearly as effective as patching, with visual acuity improvements of 1.5 and 1.8 logMAR lines, respectively.²⁹ Both trials reported that few participants experienced ocular and systemic side effects such as light sensitivity, irritation, urinary urgency, confusion, and dry mouth. Rather, atropine was safe for most of the participants to successfully continue treatment.

When comparing the quality of life of parents of children with amblyopia, atropine was found to have fewer negative impacts than patching, particularly in terms of adverse effects, adherence, and social stigma.¹⁰ However, from the children's perspectives, both treatments were well tolerated, and neither was preferred over the other.^{30,31} Despite this, there is no conclusive evidence that adherence to atropine is better than patching, as objective adherence to atropine has not been as thoroughly investigated. Limited objective data on atropine adherence exists, with a pilot study reporting an average adherence rate of 88% using a medication event monitoring system (MEMS).³² Another study presented at an annual meeting indicated that adherence to atropine drops decreases over time.³³

Bangerter Filters

In 1953, Bangerter invented a transparent foil designed to be applied to the inner part of the spectacle lens of the sound eye. This treatment (Bangerter foils) prevents partial light from entering the non-amblyopic eye to blur its image and cause penalization, thereby forcing the use of the amblyopic eye.³⁴ In 2010, the Pediatric Eye Disease Investigator Group, in a randomized clinical trial, compared the effectiveness of Bangerter filters and patching in treating children 3 to < 10 years old with moderate amblyopia.³⁵ A total of 186 children were randomized to receive either 2 hours/day of patching, or a Bangerter filter over the spectacle lens of the fellow eye (density was adjusted to 0.2 for amblyopia of 20/80, and 0.3 for amblyopia from 20/40 to 20/63). Mean visual acuity improvement after 24 weeks in the amblyopic eyes was 1.9 logMAR lines in the Bangerter filter group and was 2.3 logMAR lines in the patching group. The difference between the two groups was not statistically significant. Thirty-eight percent of the Bangerter filter group had improvement of ≥ 3 logMAR lines while 35% in the patching group had ≥ 3 logMAR lines. The study concluded that both treatments had similar visual acuity improvement, and there was a lower burden on parents and children who received the Bangerter filters.

In a subsequent study using the same dataset, visual acuity in the non-amblyopic eyes was investigated to determine the ability of the Bangerter filter densities to produce a blurry image that was worse than the amblyopic eyes.³⁶ Filter densities used in the above-mentioned study were 0.2 for amblyopic eyes of 20/80, and 0.3 for amblyopic eyes of 20/40 to 20/63 visual acuity. The study found that the 0.2 and 0.3 filters degraded visual acuity in the non-amblyopic eyes by mean of 5.1 logMAR lines, and 4.8 logMAR lines, respectively. The study concluded that the visual acuity degradation caused by the 0.2 and 0.3 filters was sufficient to produce a blurry image that was worse than the amblyopic eyes.

Recent systematic reviews reaffirmed the effectiveness of Bangerter filters as a viable alternative to patching, particularly for families seeking less disruptive treatment options. Also, Bangerter filters were well-tolerated by children and showed comparable long-term outcomes to traditional occlusion therapy, with added benefits of better adherence and fewer psychosocial impacts on the child and family.^{37–39} These findings suggest that Bangerter filters remain a relevant and effective treatment option in the management of moderate amblyopia, providing a balance between efficacy and patient comfort.

Binocular Treatment

In the 1970's, vision scientists suggested that occlusion treatments do not adequately treat the primary deficit associated with amblyopia, which is binocular dysfunction, causing abnormal binocular interaction.^{40–43} Researchers claimed that to treat amblyopia more efficiently it was important to perform amblyopia therapy with both eyes open.⁴⁴ Vision scientists developed different anti-suppression techniques that enhance monocular and binocular visual processing. For example, monocular fixation in the binocular field is a binocular task in which the amblyopic eye is engaged in a visual task, while the fellow eye is open, but not fully engaged in visual processing. Over time, the clinician increases the engagement of the fellow eye and the goal is to reduce and eventually eliminate the suppression response from the amblyopic eye under binocular conditions.⁴⁴ Cohen in 1981, stated that "the important concept is that the amblyopic eye is made to be the lead eye in the binocular act, and that we are able to develop true binocular integration with suppression controlled during saccadic, accommodative changes, visual memory, etc. and thus extend these skills to everyday.⁴⁴

Over the last two decades, various new binocular treatment techniques have been investigated, including dichoptic training, contrast balancing, video games, and passive viewing. Early studies, such as those conducted by Hess et al, showed promising results with small sample sizes, reporting improvements in both visual acuity and stereoacuity. For example, Hess et al in 2010, used goggles that reduced contrast in the fellow eye to 10%, and increased it in the amblyopic eye to 100%. Then, they increased the contrast in the fellow eye slowly after several visits until both eyes have the same level of contrast. Nine adult amblyopes received dichoptic training of 5 to 52 hours. The authors found that participants had a mean improvement in visual acuity of 0.26 logMAR, and 8 out of 9 participants had an improvement in stereoacuity.⁴⁵ Birch et al conducted a study to investigate a similar approach where children watched 6 movies during 2 weeks with dichoptic glasses that reduced contrast over the sound eye.⁴⁶ The authors reported that 81% of children had an improvement of 1 to 2 logMAR lines after 2-weeks of passive viewing. Also, the percentage of children with severe amblyopia decreased from 30% to 11% by the end of the treatment.

Recent randomized clinical trials have provided mixed results regarding the effectiveness of binocular treatment compared to traditional patching. For instance, the Pediatric Eye Disease Investigator Group found that binocular treatments were generally less effective than patching in children aged 5 to 13 years and in teenagers aged 13 to 17 years.^{47,48} Furthermore, a 2019 trial found that even when using a more engaging video game, binocular treatment did not outperform spectacles alone.⁴⁹ This trial is an important piece of evidence that adds to the understanding that while binocular treatments hold potential, they often do not outperform traditional methods like patching or even spectacles alone in improving visual acuity in amblyopic children.

Recent research highlights the ongoing issue of poor adherence to binocular treatments for amblyopia, which has significantly impacted their effectiveness. Studies such as the BRAVO clinical trial and research by the Pediatric Eye Disease Investigator Group (PEDIG) found that adherence to home-based binocular videogame treatments was low, with only a small percentage of participants completing the prescribed treatment. For instance, in the PEDIG study, only 22% of participants adhered to more than 75% of the prescribed treatment, leading to minimal improvements in visual acuity.⁵⁰ Another study on adherence patterns revealed that game sessions were typically short, interspersed with frequent pauses, which hindered the effectiveness of the treatment requiring sustained visual stimulation.⁵¹ These findings underscore the challenge of maintaining adherence in binocular treatments, affecting their overall success in treating amblyopia.

Emerging therapies for amblyopia are addressing the needs of children today and future generations by offering innovative, engaging, and effective treatment options. CureSight and Luminopia are two innovative approaches that leverage technology to overcome common challenges with adherence and target both visual acuity and binocular function. CureSight uses eye-tracking technology to adjust visual stimuli dynamically while monitoring adherence remotely,²⁴ and Luminopia modifies popular video content into a therapeutic experience that balances visual input between the amblyopic and fellow eye.²³ Both aim to provide child-friendly alternatives to traditional treatments like patching and atropine.

CureSight treatment has shown promising results in improving visual acuity and binocular function, offering a modern and engaging approach to amblyopia therapy. However, in CureSight trials, the control group followed a standard patching regimen of 2 hours per day, while the CureSight group had fewer total treatment hours per week. This reduced treatment burden likely contributed to better adherence in the CureSight group, giving it a notable advantage. Additionally, adherence for CureSight was objectively monitored, whereas the patching group relied on self-reported data, which is less reliable. The trials were also relatively short, lasting only 16 weeks, and excluded children with severe amblyopia or significant strabismus, limiting the generalizability of the findings.⁵²

Similarly, Luminopia trial demonstrated significant improvements in visual acuity compared to a control group using glasses correction.⁵³ However, glasses are less effective than standard treatments like patching, which likely made Luminopia appear more favorable in comparison. Luminopia also required fewer treatment hours, which likely contributed to higher adherence. As with CureSight, adherence for Luminopia was tracked objectively, while the control group relied on self-reports, introducing potential bias. The short follow-up periods and exclusion of older children or those with severe amblyopia limit how well the findings reflect real-world treatment scenarios.

CureSight and Luminopia represent a new era in amblyopia treatment, offering innovative ways to improve adherence and target binocular vision. However, previous studies face important limitations, such as differences in treatment burden, reliance on self-reported adherence in control groups, and short follow-up durations. Independent, longer-term studies with more diverse populations are essential to fully establish their role in the broader management of amblyopia. Also, it is crucial to consider the ethical implications of increased screen exposure in young children, particularly its potential impact on behaviour and psychological development.⁵⁴

Perceptual Learning

Another treatment approach is called perceptual learning. The rationale behind the use of perceptual learning is that repeated visual tasks produce permanent sensory changes in the visual cortex of adults, which suggest neural plasticity in older individuals.⁵⁵ Visual perceptual learning was designed mainly for amblyopic adults and older children with residual amblyopia. The amblyopic participant is asked to make subtle visual discriminations with the amblyopic eyes (the other eye is occluded) over many hours of repeated experience. It is thought that this approach is similar to patching because it is performed while the fellow eye is occluded.⁵⁶ Roger et al in 2011, showed promising results with this treatment. They used perceptual learning to treat 20 amblyopic participants 15 to 61 years old. The authors found that amblyopic participants who tried action and non-action video games 40–80 hours (2 hours/day) had an average improvement of 1.6 and 1.4 logMAR lines for crowded and single letters charts, respectively. The authors also found that 5 participants had an average improvement in stereoacuity of 53.6%.⁵⁷ Levi in 2012, however, stated that amblyopic adults who practiced perceptual tasks for 40–50 hours improved only 0.1–0.2 logMAR.⁵⁸ Birch stated that there could be two possible reasons to explain the limitations of this approach. First, this treatment requires a long time of engagement, and most adults showed low adherence to it. Second, little improvement in visual acuity was reported which makes it incomparable to the occlusion treatments.⁵⁶

While similar to patching in its goal of isolating the amblyopic eye, perceptual learning primarily serves as a complementary treatment rather than a standalone solution. A 2021 pilot study demonstrated that combining perceptual learning with occlusion therapy can significantly improve outcomes in children who had not responded well to patching alone, further underscoring its role as a supplementary treatment.⁵⁹ Similarly, Zheng et al found that network-based perceptual learning (NBPL), when paired with patching, led to substantial gains in both visual acuity and stereoacuity, particularly enhancing stereoacuity beyond what traditional methods alone could achieve.⁶⁰ Shah et al also supported this complementary approach, showing that perceptual learning significant improvements in both visual acuity and stereopsis.⁶¹ These findings suggest that while perceptual learning is a valuable treatment for amblyopia, its true strength lies in its ability to enhance the effectiveness of traditional therapies, offering a more comprehensive approach to managing the condition.

Intermittent Occlusion Therapy (IO-Therapy)

In 1994, Blinov et al introduced the various optical applications of Ferroelectric Liquid Crystals such as TV screens and watches.⁶² By utilizing the electro optical properties of liquid crystalline materials, Ben-Ezra in 2003 invented the Amblyz (IO-therapy) glasses to provide intermittent occlusion treatment for amblyopia.⁶³ IO-therapy is a new approach to amblyopia therapy that was mainly developed to overcome adherence issues. Electronic occlusion associated with the

IO-therapy glasses provides intermittent occlusion and eliminates the need for adhesive patching, eliminating the issues related to adhesive patching. These glasses can be programmed to switch between opaque and transparent phases, in 30-second intervals, over the non-amblyopic eye. If needed, a clip-in carrier, can also be attached to the glasses for spectacle correction. The aim is to provide occlusion of one eye, 50% of the time while worn. The intermittent nature of this occlusion is designed to minimize the constant blur associated with continuous occlusion that occurs with patching or atropine. The hope is that this will improve treatment adherence.

The feasibility and safety of these glasses were studied.^{63–66} Ben-Ezra et al, in 2007, used IO-therapy glasses to evaluate its effectiveness and safety to treat unilateral amblyopia. Ten participants, 5.4 to 8 years old, with unilateral amblyopia were enrolled and treated with IO- therapy glasses. Follow-up visits were scheduled after 5 weeks to assess visual acuity (distance and near), adverse effects, and adherence. The study reported no adverse effects and children were not negatively impacted while performing activities of daily living.⁶³ In 2014, these glasses were approved by the US Food and Drug Administration as a medical device to treat amblyopia.

Three studies have investigated the effectiveness of intermittent occlusion (IO) therapy in treating unilateral amblyopia. In 2010, Spierer et al conducted a study with 24 amblyopic children aged 4 to 7.8 years with moderate unilateral amblyopia. Without a control group, they found that after 9 months, 79% of participants had a visual acuity improvement of 3 lines or more, and 21% showed significant improvement in stereoacuity.⁶⁴ In 2015, Ibrahim et al studied 14 amblyopic participants aged 6 to 8.8 years with moderate to severe unilateral amblyopia. Over 4 to 7 months, participants underwent 4 to 12 hours of IO-therapy, resulting in an average visual acuity improvement of 3 lines (0.3 logMAR).⁶⁵ However, the lack of a refractive adaptation period before IO-therapy raised concerns that the improvement might be due to refractive correction rather than the therapy itself. Finally, in 2016, Wang et al conducted the first randomized clinical trial comparing IO-therapy and patching in 34 participants aged 3 to 8 years with moderate unilateral amblyopia. After 12 weeks, both groups showed an average improvement of 0.15 logMAR in visual acuity, leading the authors to conclude that IO-therapy is not inferior to continuous occlusion.⁶⁶

Despite the promising results of IO-therapy, there is a notable lack of randomized controlled trials (RCTs) to further validate this treatment as a reliable option for unilateral amblyopia. The limited number of studies makes it difficult to draw definitive conclusions about its efficacy in comparison to constant occlusion. Additionally, the main goal of IO-therapy is to avoid the use of adhesive patching and provide intermittent occlusion that does not disrupt the child's daily activities and therefore improve adherence to amblyopia treatment. However, our unpublished pilot data indicates that adherence to IO-therapy was as low as 48%.^{67,68}

Strategies Targeting Children to Improve Adherence to Patching Therapy

Research over the years has consistently shown the effectiveness of educational cartoons and programs in improving adherence to amblyopia treatment in children. Early studies demonstrated the value of these interventions, particularly in populations where adherence is typically low. For example, a 2006 study utilized an educational program that included a cartoon story, reward stickers, and an information leaflet for parents. This study found that the educational intervention significantly improved adherence to patching treatment, especially among children with poor initial adherence due to factors like low parental fluency in the national language or low levels of education.¹⁸ Similarly, a 2012 study found that implementing an educational cartoon significantly improved adherence to occlusion therapy, particularly among children from low socioeconomic backgrounds and immigrant families who spoke the local language poorly. This study high-lighted the power of visual storytelling to bridge communication gaps and enhance understanding, leading to better treatment outcomes.⁶⁹ Another randomized trial confirmed that the educational cartoon was more effective in improving adherence compared to other tools like reward calendars and informational leaflets.⁷⁰

Building on this foundational research, a 2014 randomized controlled trial introduced an intense educational and motivational intervention aimed at improving adherence to a high-dosage patching regimen. The study showed that this intervention, which included educational cartoons, significantly increased adherence rates from 45.2% in the control group to 80.6% in the intervention group. The study highlighted improved adherence with educational tools but questioned its impact on treatment outcomes, showing no significant difference in visual improvement between groups. However, this trial has a few important limitations that deserve attention. The small sample size might have made it

harder to detect meaningful differences in visual outcomes between the groups, even though adherence was better in the intervention group. The decision to prescribe a strict 10-hour-per-day patching regimen for all levels of amblyopia did not seem well-justified and may have placed unnecessary stress on both the children and their families. This added burden likely played a role in the high dropout rate in the control group, where 11 participants did not complete the study. These dropouts may have left gaps in the follow-up data, making it harder to fully understand how adherence influences visual improvement.⁷¹

Furthermore, a 2016 systematic review and meta-analysis evaluated various interventions to increase adherence to patching treatment in children with amblyopia. This review highlighted that interventions including an educational element were more effective in improving adherence compared to other strategies, underscoring the critical role of education in successful treatment outcomes.⁷² More recently, in 2023, a study reinforced these findings by showing that a short 4-minute educational cartoon video could dramatically improve adherence rates in children undergoing patching therapy, further validating the role of educational media in enhancing treatment adherence.⁷³ These studies collectively demonstrate that educational interventions, particularly those using engaging and child-friendly formats like cartoons, are highly effective in promoting adherence to amblyopia treatment in children. All these studies share a significant limitation in their design: the long-term impact of the educational interventions remains unknown. Since amblyopia treatment can extend over several years, it is crucial to assess the long-term effectiveness of these strategies to enhance adherence to amblyopia treatment. This will help to determine whether children require repeated education throughout the treatment process.

Strategies Targeting Clinicians and Parents to Improve Adherence to Patching Therapy

Tripathi et al demonstrated the importance of parental involvement in the treatment process by allowing them to choose between different occlusion regimens.⁷⁴ This approach significantly improved adherence, especially among parents who had no prior experience with occlusion therapy. By giving parents, the autonomy to select a regimen that best fit their lifestyle, the study showed that treatment adherence could be enhanced, leading to more successful outcomes for children with amblyopia. This finding underscores the need to consider parental preferences and involvement in treatment planning.

Building on the idea of enhancing parental involvement, a randomized controlled trial was conducted to evaluate the impact of providing written information to parents on their adherence to occlusion therapy.⁷⁵ The study revealed that parents who received detailed written information were less likely to exhibit non-concordance with the prescribed therapy, emphasizing the importance of clear communication from healthcare providers. Similarly, Loudon et al high-lighted that nonadherence was significantly associated with factors like poor parental fluency in the national language and lower levels of education.¹⁸ They found that educational programs tailored to these specific challenges could effectively improve adherence, particularly in vulnerable populations.

Further reinforcing the role of education and clinicians' support, another study found that supervised occlusion treatment, combined with parental education, significantly improved adherence in children who had previously failed outpatient treatment.⁷⁶ This is in line with the findings of Iturriaga et al, who demonstrated that frequent evaluations and regular follow-ups offer more opportunities to enhance adherence through consistent monitoring and support.⁷⁷ Together, these studies highlight the effectiveness of combining educational interventions with regular clinician-parent interactions to maximize treatment adherence in amblyopia therapy (Table 1).

The AmblySmart Glasses to Optimize Adherence to Amblyopia Treatment

Currently, no device or technique exists that guarantees consistent adherence to eye covering throughout the treatment period for children. There remains a need for a device or method that performs the same function as the traditional treatment of covering the good eye but is equipped with more attractive features that motivate the child to stick to the treatment. Thus, we hypothesize that a device integrating modern technology and engaging features, such as leveraging children's screen time, could significantly improve adherence to amblyopia and refractive error treatment. (PAT: SA121430076B1) (IPC: A61F 9/000).

Study (Year)	Intervention	Key Outcome	Relevance
Tripathi et al ⁷⁴ (2002)	Parental choice of regimen	Enhanced adherence by involving parents in decision-making	Emphasizes parental autonomy as a factor in adherence
Loudon et al ¹⁸ (2006)	Educational program (cartoon, stickers, leaflet)	Improved adherence in children with poor initial compliance	Highlights the role of multi-faceted educational tools targeting both children and parents
Tjiam et al ⁶⁹ (2012) Tjiam et al ⁷⁰ (2013)	Educational cartoon, reward calendars and informational leaflets.	Increased adherence, especially in low socioeconomic and immigrant families	Demonstrates the effectiveness of visual storytelling to overcome communication barriers
lturriaga et al ⁷⁷ (2012)	Supervised treatment with parental education	Improved adherence with consistent follow- up and monitoring	Reinforces the need for clinician involvement alongside education
Pradeep et al ⁷¹ (2014)	Motivational intervention with cartoons	Adherence improved from 45.2% to 80.6%	Shows that combining education with motivation significantly enhances adherence
Dean et al ⁷² (2016)	Systematic review and meta- analysis	Educational strategies found most effective	Confirms the importance of educational interventions across studies
Aljohani et al ⁷³ (2023)	4-minute educational cartoon video	4-minute educational cartoon video improve adherence rates in children undergoing patching therapy	Supports the use of brief, engaging educational media for adherence

Table I Summary of Key Educational and Parental Involvement Strategies to Improve Adherence to Patching Therapy in Children

The AmblySmart glasses utilizes the time a child spends using smart devices (eg, tablets, smart phones, smart TVs, videogames) to treat amblyopia by optimizing adherence to the prescribed occlusion time. This is achieved through the enforced coupling of the child wearing the glasses, which covers the healthy eye, while simultaneously operating their preferred smart devices. The glasses include a set of built-in sensors precisely integrated and distributed at the contact points between the glasses and the child's skin (Figure 1). The glasses are designed to pair with a smart device with a screen through a pre-programmed application that controls the opening and closing of the device's screen. The smart device's screen is only accessible when the child correctly wears the smart glasses, ensuring that all six sensors are in contact with the skin. The screen closes if the glasses are removed or if the child attempts to view the screen outside the lens frame.

The glasses' application is installed on the smart device, allowing the glasses to be paired with the device. The application also sets a specific duration for the child to wear the glasses. When the child dons the glasses, the sensors send signals to the smartphone application, indicating that the glasses are being worn, which prompts the application to unlock the device's screen.

Conversely, if the glasses are removed or not worn correctly, the sensors trigger a lost connection with the smart device's application, indicating an error, causing the screen to lock, accompanied by a notification urging correct usage of the glasses. However, if the child properly re-wears the glasses, the screen unlocks again (Figures 2 and <u>S1</u>).

When the predetermined glasses-wearing time ends, the application notifies that the time has elapsed, but the screen remains accessible to the child even after the glasses is removed. This innovation effectively links the time required to cover the eye for amblyopia treatment with the time the child spends in front of screens. Thus, the glasses, with the precisely distributed sensors as described in the current invention, ensures that the child adheres to the time intervals prescribed by the doctor or specialist for covering the healthy eye, thereby stimulating the weaker eye. While smart device-linked interventions such as AmblySmart offer promising improvements in treatment adherence, it is also important to acknowledge potential ethical considerations, including the risk of increased screen time and the need to ensure robust safeguards for child privacy and data security.

Conclusion

In summary, adherence to amblyopia treatment remains a significant challenge despite the effectiveness of traditional methods such as patching and atropine penalization. Various factors, including treatment discomfort, social stigma, and child-specific characteristics, contribute to poor adherence. This review has evaluated numerous alternative treatments and strategies aimed at

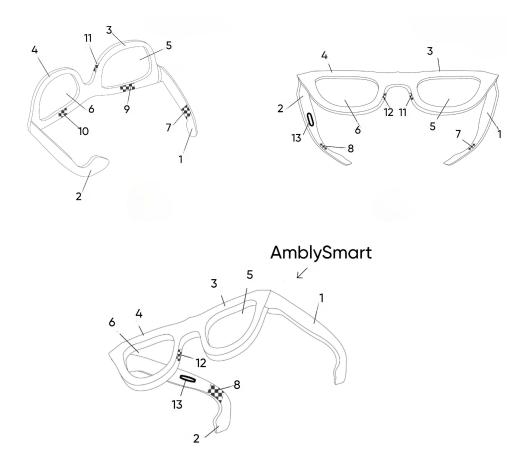


Figure 1 Shows the six sensors' positions that are precisely integrated and distributed at the contact points between the glasses and the child's skin. Sensors (11) and (12) touch the two sides of the nose, sensors (9) and (10) touch at the two eyebrows, and sensors (7) and (8) touch above the two ears. The action of each pair of sensors follows a standby mechanism for a maximum flexibility.



Figure 2 Shows a simulation for what will happen when a child refuse wearing the AmblySmart glasses. This will be the case for all smart screens including tablets, TVs, and videogames.

improving adherence, including the use of Bangerter filters, binocular therapies, educational interventions, and innovative technologies like intermittent occlusion therapy glasses. While these alternatives show promise, particularly in reducing treatment-related discomfort and improving psychosocial acceptance, they do not universally outperform traditional methods.

The introduction of the AmblySmart glasses offers a novel approach by leveraging children's screen time to optimize treatment adherence. By integrating sensor-based technology that ensures proper wearing of the glasses during screen use, this innovation has the potential to enhance adherence without the need for constant monitoring. However, it is still too early to determine the practicality and effectiveness of this approach compared to traditional methods. Further studies are needed to establish its clinical value before direct comparisons can be made. Additionally, there remains a pressing need to develop innovative treatment strategies for amblyopia that align with the lifestyles and preferences of children growing up in an increasingly digital world.

Data Sharing Statement

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Disclosure

Dr Saeed Aljohani owns the patent entitled The AmblySmart (Motivational glasses to treat amblyopia in children), that is granted from the Saudi Authority for Intellectual Property (PAT: SA121430076B1) (IPC: A61F 9/000).

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