Effectiveness of Telescopic Magnification in the Treatment of Amblyopia

A Pilot Study

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Objective: To compare the effectiveness of patching plus telescopic magnification vs patching alone in treating refractory amblyopia.

Methods: Children aged 4 to 17 years who failed previous amblyopia treatment were recruited into this prospective study. Subjects were randomly assigned to either 30 minutes per day of patching of the fellow eye only (n=7) or 30 minutes per day of patching of the fellow eye plus concurrent use of a telescope in the amblyopic eye (n=8).

Main Outcome Measure: Best-corrected logMAR visual acuity score of the amblyopic eye after 17 weeks of treatment.

Results: Both treatment groups demonstrated significant improvement in visual acuity in the amblyopic eye after 17 weeks ($P=.001$). Improvements in the patching-only group were slightly greater over the course of treatment, but this difference was not statistically significant ($P=.06$). At 17 weeks, mean visual acuity improvement from baseline was 0.14 logMAR (SD, 0.13 logMAR) in the patching-only group and 0.06 logMAR (SD, 0.17 logMAR) in the patching plus telescope group ($P=.11$). The 17-week visual acuity was at least 0.2 logMAR and/or improved from baseline by at least 0.2 logMAR in 2 patients in the patching-only group and none in the patching plus telescope group ($P=.08$).

Conclusion: Treatment of refractory amblyopia in children using telescopic magnification did not appear to confer any additional benefits over patching alone.

Application to Clinical Practice: Occlusion and penalization remain the standard of care for patients with amblyopia and should remain the benchmark against which other treatments are compared in clinical trials for amblyopia therapy.

Trial Registration: clinicaltrials.gov Identifier: NCT00970554

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Amblyopia is visual impairment of 1 eye that results from its disuse during early brain development.[1] It is the number one cause of monocular blindness and affects about 1% to 4% of the general population.[2-8] Amblyopia is most commonly associated with early childhood strabismus, anisometropia, or, more rarely, image degradation from high-isometropic ametropia, congenital cataract, or ptosis. It has been estimated that, in the United States alone, untreated amblyopia causes an annual loss of $7.4 billion in earning power and a corresponding decrease in gross domestic product.[9] An estimated $341 million is spent each year to prevent and treat the disease.[9]

The standard treatment for amblyopia consists of patching or pharmacological penalization of the fellow eye. Typically, the earlier the treatment is initiated, the higher the chance of visual recovery. Unfortunately, approximately 50% of children with amblyopia do not respond to these therapies, with poor compliance being a major factor in treatment failure.[10-14] Better treatment options that enhance compliance are therefore needed to improve the visual impairment caused by amblyopia.

One new treatment strategy involves patching the fellow eye while using a telescopic device on the amblyopic eye to magnify the images formed.[15] Currently, telescopes are used predominantly as vision aids in those with low vision or age-related macular degeneration.[16] The magnification offered by a telescope may facilitate object recognition in the amblyopic eye by lowering the spatial frequency content of the image components to a range that is more readily detectable, thereby enhancing patient compliance with the therapy.

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Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria
Age 4-17 y
Strabismic, refractive (anisometropic), mixed mechanism, or high-isometropic hyperopic amblyopia
Strabismic amblyopia: amblyopia (1) in the presence of either an inability to maintain parallel visual axes (heterotropia) at distance and/or near fixation or a history of strabismus surgery (or botulinum injection), and (2) in the absence of refractive error, meeting the criteria for mixed mechanism amblyopia
Refractive/anisometropic amblyopia: amblyopia in the presence of a difference in refractive error between the 2 eyes (anisometropia) of ≥0.5 D of spherical equivalent or ≥1.5 D of difference in astigmatism in any meridian, with no measurable heterophoria at distance or near fixation, which persisted after 12 weeks of spectacle correction
High-isometropic hyperopic amblyopia: amblyopia in the presence of a refractive error of ≥5.0 D of spherical equivalent in both eyes, but not meeting the criteria of anisometropic amblyopia
Mixed mechanism strabismic and refractive amblyopia: the presence of both strabismic and anisometropic types of amblyopia
Ability to read the ETDRS letter chart
Visual acuity of 0.3-1.3 logMAR (20/40-20/400) in the amblyopic eye
Visual acuity of 0.3 logMAR (20/40) or better in the healthy eye
Interocular acuity difference of ≥0.3 logMAR
Appropriate refractive error correction for ≤12 wk
Exclusion Criteria
Presence of an ocular cause of reduced visual acuity
Myopia with a spherical equivalent of ≥−6.0 D owing to the likely presence of pathological myopia
Prior intraocular surgery
Known skin reaction to patch or bandage adhesive

Abbreviations: D, diopters; ETDRS, Early Treatment Diabetic Retinopathy Study.

Nazemi et al[15] recently investigated the use of telescopic magnification in 17 patients aged 7 to 16 years with anisometropic amblyopia who had failed previous treatment. They found an improvement in visual acuity of at least 2 lines in 100% of patients, with 69% of patients with moderate amblyopia (visual acuity <20/80) achieving 20/25 visual acuity and 40% of patients with severe amblyopia (>20/100) achieving 20/40 visual acuity. These findings were extraordinary for several reasons. First, these results compared very favorably and surpassed those reported previously from a large multicenter study that compared optical correction alone vs optical correction and patching/penalization.[12] Second, these patients responded to telescopic treatment despite having failed previous amblyopia therapy. Third, these patients were older children who were generally considered to be more difficult to treat because they were beyond the traditional critical period.[17] There is evidence, however, that unlike those with deprivation or strabismic amblyopia, patients with anisometropic amblyopia may still respond to therapy in adolescence and adulthood.[12,18-20] A major limitation of the study by Nazemi et al[15] was its lack of a control group. Specifically, the observed improvements in older patients with anisometropic amblyopia may have been due to another cycle of patching and not to any specific effects of the telescope. The goal of the present investigation was to conduct a prospective randomized clinical study to further evaluate the effectiveness of telescopic magnification plus patching vs patching alone on different types of amblyopia in patients who had failed previous treatment.

METHODS

All patients aged 4 to 17 years who had failed previous treatment for amblyopia were recruited from The Hospital for Sick Children in Toronto, Canada, between December 2007 and February 2009. Only patients who were noncompliant with previous treatment and those who failed to show any improvement after 3 cycles of patching or penalization (each cycle lasted 1-3 months according to the patient's age and daily duration of treatment) were included. Other inclusion and exclusion criteria were similar to those used in several large multicenter studies[10-14] and are presented in **Table 1**.

Children were randomized to receive solely daily patching of the fellow eye for 30 minutes (patching-only group) or daily patching of the fellow eye for 30 minutes plus simultaneous use of a telescopic device in the amblyopic eye (patching plus telescope group). Randomization was accomplished by a computer-generated sequence of random numbers that was concealed and kept by one of the investigators (G.M.) until interventions were assigned to patients by another investigator (F.N., J.W., or J.S.). Patients were encouraged to watch their favorite television show or engage in their favorite activities during treatment. Telescopic magnification was achieved by using an adjustable galilean telescope with a ×2.2 magnification attached with a wire clamp to the glasses over the amblyopic eye.

After informed consent was obtained, a complete eye examination, including measurement of best-corrected visual acuity, stereoacuity, ocular motility, and cycloplegic refraction, was performed. Visual acuity was tested monocularly using the Early Treatment Diabetic Retinopathy Study (ETDRS) logMAR acuity chart (Vector Vision, Arcanum, Ohio) at 3 m with best correction. The logMAR score was recorded as the log unit of the minimum angle of resolution of the last row in which a patient could correctly read all 5 letters. For each letter that was identified correctly beyond the last row, 0.02 log units were subtracted. Lower scores indicate better acuity, with 0.0 logMAR representing visual acuity of 20/20. For example, if a patient read the 0.6 logMAR (20/80) row completely and 2 letters from the next row, the visual acuity was recorded as 0.56. Stereoacuity was measured by the Titmus stereotest. Cycloplegic refraction was performed on all patients and new glasses were prescribed if needed. No patients except one needed new glasses (this patient wore them >12 weeks), and therefore they were assigned to either treatment group immediately. One patient required a new glasses prescription for high-isometropic

Table 2. Baseline Characteristics of Patients

Characteristic	No. of Patients: Patching Only (n = 7)	Patching Plus Telescope (n = 8)
Sex		
M	5	8
F	2	0
Age, mean (SD), range, y	8.7 (3.5), 5-15	7.1 (1.9), 4-10
Affected eye		
Right	4	5
Left	3	3
Amblyopia type		
Strabismic	3	1
Anisometropic	2	2
Mixed mechanism	2	4
High-isometropic hyperopia		1
Baseline VA of amblyopic eye, mean (SD), logMAR	0.73 (0.24)	0.84 (0.31)
Baseline VA of fellow eye, mean (SD), logMAR	0.03 (0.08)	0.04 (0.07)
Stereopsis	Strabismic amblyopia: 3000 seconds of arc in 1, no stereopsis in 2 Anisometropic amblyopia: 80 seconds of arc in 1, no stereopsis in 1 Mixed mechanism amblyopia: 3000 seconds of arc in 2	Strabismic amblyopia: no stereopsis in 1 Anisometropic amblyopia: 400 seconds of arc in 1, no stereopsis in 1 Mixed mechanism amblyopia: 3000 seconds of arc in 1, no stereopsis in 3 Isometropic hyperopia: no stereopsis in 1

Abbreviation: VA, visual acuity.

hyperopia, and he was assigned to the patching plus telescope group after wearing the new glasses for 12 weeks when his vision did not improve. For those who did not have any refractive error and were randomized to receive telescopic magnification treatment, glasses with plano lenses were prescribed so that the telescope could be clipped onto the frame of the glasses. An orthoptist checked the positioning of the telescope while each patient in the patching plus telescope group wore the glasses and explained to the parents or caregivers in detail the proper positioning of the telescope and its importance.

During follow-up visits at 5 and 17 weeks (visit window, ±1 week), the best-corrected logMAR visual acuity score was recorded at each visit, with additional follow-up at the discretion of each referring physician. At each visit, the parents or caregivers were asked about skin irritation from patching or any other adverse effects from patching or the telescope. All parents or caregivers reported that the patients had complied with the prescribed treatment. The patients, parents or caregivers, and investigators were by the nature of this pilot study unmasked to the treatment group assignments and the clinical status of the patients, including the primary visual acuity outcome measurement.

The primary outcome was the logMAR visual acuity score of the amblyopic eye at 17 weeks. The 2 treatment groups were compared using repeated-measures analysis of variance. Baseline factors (including age, type of amblyopia, and visual acuity in the amblyopic eye) were compared between treatment groups using 2-tailed *t* tests with Bonferroni correction. The same methods were used to analyze the 5-week visual acuity score of the amblyopic eye. A prespecified secondary outcome was visual acuity of at least 0.2 logMAR (20/30) and/or improvement from baseline of at least 0.2 logMAR at 17 weeks in the amblyopic eye. The number of patients with visual outcomes that met these criteria was compared between the 2 treatment groups using a 2-tailed Fisher exact test. All analyses followed the intention-to-treat principle (ie, the treatment group data were based on the randomization assignments, not on the actual treatment received or whether the treatment protocol was followed). Significance level was set at $P < .05$. Analyses were conducted using SAS, version 8.2 (SAS Institute Inc, Cary, North Carolina). Data are expressed as mean (standard deviation) unless otherwise noted.

RESULTS

Fifteen patients who had failed previous amblyopia treatment were recruited, with 7 assigned to the patching-only group and 8 to the patching plus telescope group. All patients received the intended treatment and completed the study protocol, and their outcome measures at 5 and 17 weeks were available for analyses. Overall, the mean age of patients was 7.9 years (2.8 years). Two were girls (11%). The mean visual acuity logMAR score across all patients at baseline was 0.79 (0.28) in the amblyopic eye and 0.03 (0.07) in the fellow eye. The mean interocular visual acuity difference at baseline was 0.75 logMAR (0.26 logMAR). The baseline characteristics of patients in both treatment groups are shown in **Table 2**. There was no difference in age ($P = .28$) or visual acuity in the amblyopic ($P = .47$) or fellow ($P = .82$) eye between the 2 treatment groups at baseline. One anisometropic patient in each treatment group had fine-to-moderate stereopsis (one in the patching-only group had a stereoacuity of 80 seconds of arc; the other in the patching plus telescope group had a stereoacuity of 400 seconds of arc). The rest of the patients in both groups had stereoacuity of 3000 seconds of arc (3 in the patching-only group and 1 in the patching plus telescope group) or no detectable stereopsis (3 in the patching-only group and 6 in the patching plus telescope group).

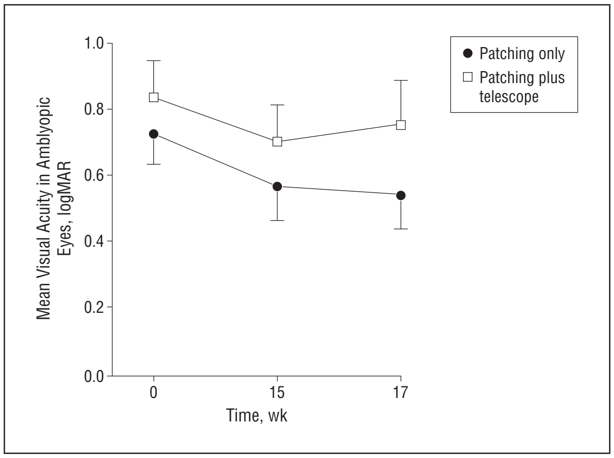

Figure. Mean visual acuity in the amblyopic eye in each treatment group at baseline and 5 and 17 weeks. Error bars denote 1 SE.

Both treatment groups demonstrated significant improvement in visual acuity from baseline at 17 weeks. Mean visual acuity at 17 weeks was 0.55 logMAR (0.26 logMAR) in the patching-only group (baseline, 0.73 logMAR [0.24 logMAR]) and 0.75 logMAR (0.36 logMAR) in the patching plus telescope group (baseline, 0.84 logMAR [0.31 logMAR]) ($P=.001$) (**Figure**). Improvements in the patching-only group were slightly greater over the course of treatment, but this difference was not statistically significant ($P=.06$). At 5 weeks, mean improvement from baseline was 0.16 logMAR (0.14 logMAR) in the patching-only group and 0.13 logMAR (0.25 logMAR) in the patching plus telescope group ($P=.44$). At 17 weeks, mean improvement from baseline was 0.14 logMAR (0.13 logMAR) in the patching-only group and 0.06 logMAR (0.17 logMAR) in the patching plus telescope group ($P=.11$). Visual acuity of at least 0.2 logMAR and/or improvement of at least 0.2 logMAR from baseline was achieved in 2 patients (33%) in the patching-only group (improvement of 0.29 logMAR in one and 0.32 logMAR in another) and none in the patching plus telescope group ($P=.08$).

At 4 months, no patient in the patching-only group and 4 (57%) in the patching plus telescope group had decreased visual acuity from baseline by 0.1 logMAR in the fellow eye ($P=.09$). One other patient in the patching plus telescope group had decreased visual acuity of 0.16 logMAR in the fellow eye. No patients were considered to have developed reverse amblyopia. No other adverse events (eg, skin allergy or diplopia) were reported.

COMMENT

A recent study[15] reported improvement in vision when a telescope was used in amblyopic eyes during patching therapy; however, because of the lack of a control group, it is unclear whether the reported change was due to another cycle of patching alone or any specific effects of the telescope. To address this issue, we performed a randomized prospective study to evaluate the effectiveness of prescribing 30 minutes of patching of the fellow eye vs 30 minutes of patching of the fellow eye plus simultaneous use of a telescope by the amblyopic eye in treating children who had failed previous amblyopia treatment. We found that amblyopia improved with both treatment regimens, but telescopic magnification did not result in any additional benefit over patching alone, neither in terms of the speed or magnitude of improvement after 17 weeks of treatment. In fact, though not statistically significant ($P=.06$), patients in the patching-only group tended to perform better, indicating that another cycle of patching may lead to some improvement even in those who had failed previous treatment. In the previous study,[15] the mean group acuity ($n=17$) improved by 0.26 logMAR (0.32 logMAR) after treatment; the power was 88.2%. Based on the effect size of the previous study,[15] we calculated that the chance (power) of the patching-only group in this study showing the same effect size of 0.26-logMAR improvement as in the previous study was 86.2%, and the chance of the patching plus telescope group in this study showing the same effect size of 0.26-logMAR improvement was 68.1%. To show a significant difference between groups given the present means and standard deviations would require a total of 114 patients. To the best of our knowledge, the current study is the first to systematically evaluate the effectiveness of a telescope in the treatment of amblyopia—a prerequisite first step to assess whether a large-scale randomized clinical trial is justified, especially since an underlying mechanism as to why telescope improves vision in amblyopia remains speculative.

The discrepancy in the findings between the current and previous study[15] might be related to a difference in studied populations. While Nazemi et al[15] included only patients with anisometropic amblyopia, we included patients with amblyopia from a variety of causes, with only 2 anisometropic patients in each treatment group. Interestingly, in our study, neither of the 2 anisometropic patients in the patching plus telescope group showed any significant improvement after 17 weeks of treatment (0.08-logMAR improvement in one and no change in another), whereas 1 of 2 anisometropic patients in the patching-only group showed an improvement of 0.29 logMAR (the other had no change). Because patients with anisometropic amblyopia may respond to therapy in adolescence and adulthood,[12,18-20] it is possible that the improvements observed in the previous study[15] may have been due to additional patching but not telescope treatment.

Another possible explanation is the status of binocular function. Binocular vision in patients with strabismic amblyopia would have been disrupted by uncorrelated binocular stimulation, whereas patients with anisometropic amblyopia might have experienced degraded visual input, but the inputs would have been concordant and binocular vision might have developed relatively normally. Indeed, in a large study of 103 children with anisometropic amblyopia,[21] 89% were found to have stereopsis. In addition, there is evidence that patients with anisometropic amblyopia and binocularity respond better to patching at a later age than those with strabismic amblyopia and no binocularity.[21-23] In the study by Nazemi et al, all patients had anisometropic amblyopia whose eye alignment was less than 8 prism diopters without having undergone any previous strabismus surgery. Although it was not specified in the previous study, these patients likely had binocularity. In the current study, however, most patients had poor (3000 seconds of arc in 3 patients in the patching-only group and 1 in the patching plus telescope group) or no (3 patients in the patching-only group and 6 in the patching plus telescope group) stereopsis, which may have contributed to the lack of significant improvement in visual acuity, compared with patients in the previous study. Furthermore, the mean pretreatment acuity of the amblyopic eyes in the current study (0.84 logMAR) was worse than that in the previous study (0.5 logMAR).[15] It is conceivable that patients with milder amblyopia and good binocular function respond better to patching plus telescope treatment than patients with more severe amblyopia and no binocular function. Although the effectiveness of telescopic magnification may be selective for patients with anisometropic amblyopia and good binocularity, further study with a proper control group and carefully documented binocular function as well as a better theoretical explanation of the underlying mechanism is necessary to investigate this possibility.

Previous large multicenter studies have shown that 2 hours of patching daily is effective for moderate amblyopia, whereas 6 hours of patching daily is effective for severe amblyopia.[13,14] The prescription of 30 minutes of patching in the current study may initially seem substandard, but it was based on 2 rationales. First, we aimed to follow the same protocol used in the study by Nazemi et al,[15] which showed that patching plus telescope for 30 minutes daily may be effective. Second, we reasoned that because these children had either failed previous treatment or were noncompliant, they would not be undergoing further treatment were they not enrolled in this study. By prescribing 30 minutes of patching with or without telescope, we aimed not only to provide additional therapy to these patients, but also to improve compliance by virtue of the short duration of treatment and by the potential change in appreciation of visual image provided by the telescope to the amblyopic eye.

Concurrent near visual activities are often prescribed during patching to stimulate the visual system, but this issue is controversial.[24-27] In this study, we encouraged children in both treatment groups to watch their favorite television show or engage in their favorite activities during treatment. We do not believe that the nature of the visual activities had any impact on our findings. This is supported by a recent randomized clinical trial that found no difference in visual acuity improvement between children who performed near activities and those who performed distance activities during patching.[27]

Why did visual acuity in amblyopic eyes improve in both treatment groups? Compliance to patching therapy may play an important role. Reported compliance rates for patching therapy varied from 41% to 59%.[10-14,28-30] A number of factors affect compliance, including the age of children at onset of patching,[31,32] whether supervision is given,[33] as well as social and economic impact on families.[34] It is plausible that by consenting to enroll formally in the current study, which required a prespecified number of follow-up visits and shorter duration of treatment daily, patients and families were more motivated to follow the treatment protocol and hence improved their compliance.

In addition, test-retest variability should be considered in evaluating any clinical change. Using electronic Early Treatment Diabetic Retinopathy Study in children aged 7 to 13 years with and without amblyopia, Cotter et al[35] concluded that a difference in visual acuity of at least 0.2 logMAR should be used to indicate that a true clinical change has occurred. Interestingly, in the present study, 2 patients in the patching-only group, but none in the patching plus telescope group, had an improvement of 0.2 or more logMAR at 17 weeks, which may suggest that true clinical improvement occurred because of patching therapy alone. However, the mean improvement of visual acuity in both treatment groups at 17 weeks was well below 0.2 logMAR (0.14 logMAR in the patching-only group and 0.06 logMAR in the patching plus telescope group) and thus the observed change may simply represent test-retest variability.

In conclusion, we compared the effectiveness of patching alone and patching plus telescope in the treatment of refractory amblyopia. Our results indicated that telescopic magnification did not appear to confer any additional advantage over patching alone.

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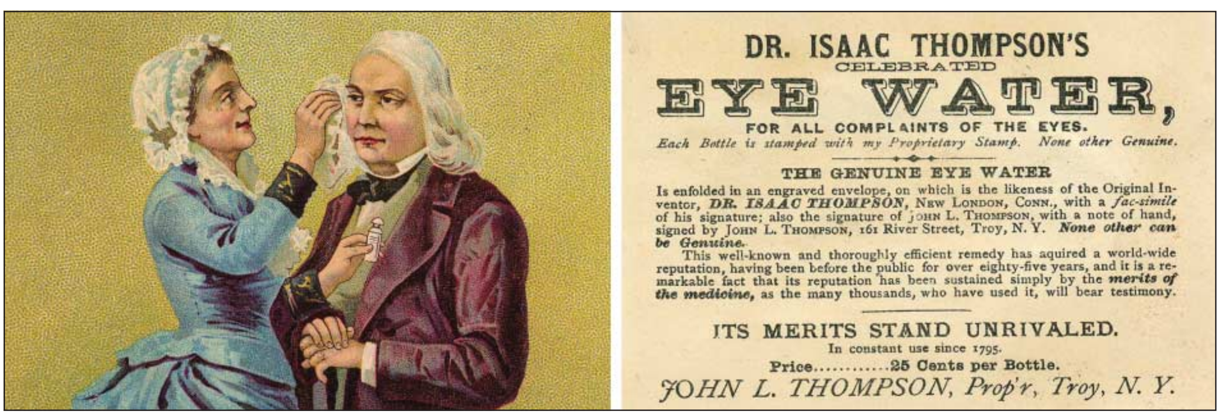
Ophthalmological Ephemera

In 1795, Dr Isaac Thompson concocted an eye water of zinc sulfate, saffron, camphor, and rose water. It was sold as late as 1939. This is 1 of a series of 32 medical trade cards advertising the product from 1875 through 1895.



Courtesy of: Daniel M. Albert, MD, MS.