Original Investigation | CLINICAL TRIAL

Randomized Crossover Clinical Trial of Real and Sham Peripheral Prism Glasses for Hemianopia

Alex R. Bowers, PhD; Karen Keeney, MSBA; Eli Peli, MSc, OD

IMPORTANCE There is a major lack of randomized controlled clinical trials evaluating the efficacy of prismatic treatments for hemianopia. Evidence for their effectiveness is mostly based on anecdotal case reports and open-label evaluations without a control condition.

OBJECTIVE To evaluate the efficacy of real relative to sham peripheral prism glasses for patients with complete homonymous hemianopia.

DESIGN, SETTING, AND PARTICIPANTS Double-masked, randomized crossover trial at 13 study sites, including the Peli laboratory at Schepens Eye Research Institute, 11 vision rehabilitation clinics in the United States, and 1 in the United Kingdom. Patients were 18 years or older with complete homonymous hemianopia for at least 3 months and without visual neglect or significant cognitive decline.

INTERVENTION Patients were allocated by minimization into 2 groups. One group received real (57–prism diopter) oblique and sham (<5–prism diopter) horizontal prisms; the other received real horizontal and sham oblique, in counterbalanced order. Each crossover period was 4 weeks.

MAIN OUTCOMES AND MEASURES The primary outcome was the overall difference, across the 2 periods of the crossover, between the proportion of participants who wanted to continue with (said yes to) real prisms and the proportion who said yes to sham prisms. The secondary outcome was the difference in perceived mobility improvement between real and sham prisms.

RESULTS Of 73 patients randomized, 61 completed the crossover. A significantly higher proportion said yes to real than sham prisms (64% vs 36%; odds ratio, 5.3; 95% CI, 1.8-21.0). Participants who continued wear after 6 months reported greater improvement in mobility with real than sham prisms at crossover end (P = .002); participants who discontinued wear reported no difference.

CONCLUSIONS AND RELEVANCE Real peripheral prism glasses were more helpful for obstacle avoidance when walking than sham glasses, with no differences between the horizontal and oblique designs. Peripheral prism glasses provide a simple and inexpensive mobility rehabilitation intervention for hemianopia.

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Author Affiliations: Schepens Eye Research Institute, Massachusetts Eye and Ear, Department of Ophthalmology, Harvard Medical School, Boston, Massachusetts (Bowers, Peli); Chadwick Optical, Inc, Souderton, Philadelphia (Keeney).

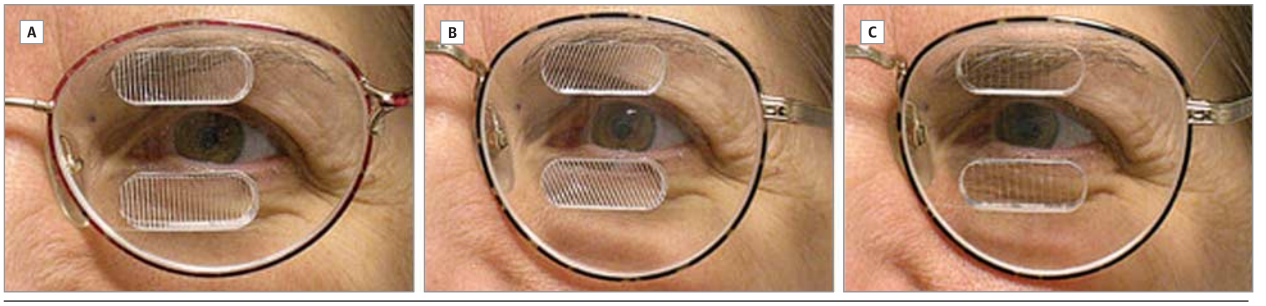
Corresponding Author: Alex R. Bowers, PhD, Schepens Eye Research Institute, 20 Staniford St, Boston, MA 02114 (alex_bowers@meei.harvard.edu).

Although prismatic corrections have been used in the rehabilitation of homonymous hemianopia (HH) for at least the last 80 years,[1] evidence for their effectiveness is almost exclusively based on anecdotal case reports[2-4] and open-label evaluations without a control condition.[5-10] Recent reviews of a range of interventions for patients with homonymous visual field loss have underscored the need for randomized controlled clinical trials in this area.[11-14] To the best of our knowledge, there have only been 3 controlled studies[15-17] of prismatic devices for HH, and each had substantial limitations (eTable 1 in the eAppendix in the Supplement).

In 2000, Peli[7] described a new approach—peripheral prism glasses—to fitting prisms for HH. High-power prism segments fitted unilaterally on the upper and lower peripheral parts of the spectacle lens provide up to 30° of lateral visual field expansion with 57-prism diopter (Δ) prisms (**Figure 1** and **Figure 2**). As the prism images fall on peripheral retina, central diplopia, common with other designs, is avoided. An evidence base for the efficacy of peripheral prism glasses has gradually been built through a series of open-label studies, including a laboratory-based study,[8] a multicenter clinical trial,[9] and most recently an independent (not initiated by Peli) single-center clinical study.[10] Clinical success rates were good in each study, with 47%[9] to 83%[10] of participants continuing to use the prism glasses in the long term, reporting that they were helpful for obstacle avoidance when walking. While these findings are promising, none of the studies included a control group or a control treatment.

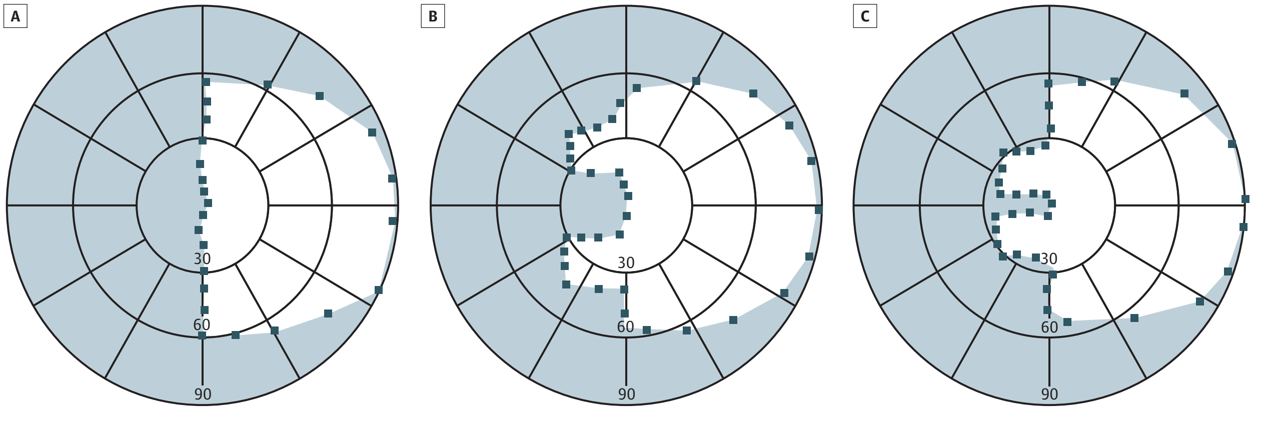
Herein, we report a controlled multicenter trial of the peripheral prism glasses using a crossover design in which each patient wore a pair of real (57Δ) and a pair of sham prism glasses (<5Δ). Our primary hypothesis was that participants would be more likely to want to continue to use the real than the sham prism glasses, because they would find them more helpful for detecting hazards when walking. Our secondary study goal was to establish preliminary comparative data on 2 peripheral prism configurations: the original "horizontal" design[7] and a more recent "oblique" design[18] (Figure 1A and B). We hypothesized that there would be no difference in continuation rates for the 2 designs because both provide visual field expansion in areas likely to be helpful when walking (Figure 2B and C). However, the oblique design may be advantageous for driving.[19]

Figure 1. Permanent Peripheral Prism Glasses as Fitted for the Study



Shown here with prisms on the left spectacle lens for a patient with left hemianopia, with 12-mm interprism separation. A, Horizontal design, 57 prism diopters (Δ) (base-apex axis horizontal). B, Oblique design, 57Δ (base-apex axis at 25°). C, Sham horizontal, 5Δ. The oblique design provided visual field expansion in more central areas of the visual field than the horizontal design (Figure 2). Each patient wore real (57Δ) prisms of one design and sham (5Δ) prisms of the other design (eg, real oblique [B] and sham horizontal [C])

Figure 2. Binocular Visual Field (Goldmann V4e) of a Patient With Left Homonymous Hemianopia



A, Without peripheral prisms. B, With 57–prism diopter (Δ) horizontal peripheral prisms. C, With 57Δ oblique peripheral prisms, as fitted for the study with a 12-mm interprism separation. Both designs provide close to 30° of lateral expansion into the blind hemifield (slightly more for the horizontal than the oblique design). The expansion is in more central areas of the field with the oblique design. Small black squares are the individual points mapped during the perimetry.

Table 1. Summary of Study Visits and Assessments

Visit[a]	Timing	Assessments and Procedures	Personnel
1	Week 0	Screening tests Spectacle and prism measurements	Practitioner
		Mobility questionnaire (baseline)	Masked data collector
2	Week 4 (approximately)	Dispense first pair of prism glasses and train in use	Practitioner
3	Week 8	Mobility questionnaire for first pair. Would you want to continue with first pair (yes/no)?	Masked data collector
		Dispense second pair of prism glasses	Practitioner
4	Week 12	Mobility questionnaire for second pair. Would you want to continue with second pair (yes/no). Comparison questionnaire (first and second pair)	Masked data collector
		Debriefing and clinical decision whether to continue wear	Practitioner
5	6 mo After visit 4	Telephone interview to assess longer-term experience of wearing prism glasses (only participants who decided at week 12 to continue)	Practitioner

[a] Visits 1 to 4 were in office; visit 5 was a telephone interview.

Methods

Schepens Eye Research Institute was the coordinating and data management center for the study. Data were collected at 13 study sites, including the Peli laboratory at Schepens, 11 vision rehabilitation clinics in the United States, and 1 in the United Kingdom. The clinics included university, hospital, and private practice clinics. Each site recruited a median of 7 participants (range, 3-12). Before screening, the nature of the study was explained and written informed consent was obtained from all participants. The study adhered to the tenets of the Declaration of Helsinki and was approved by the institutional review board at Schepens and by local institutional review boards for study sites with an institutional review board. Data were collected in the period from October 2007 to January 2010. Study visits are summarized in **Table 1**. Procedures are detailed in the eAppendix in the Supplement.

Participants

Participants were recruited by practitioners at each study site. The primary inclusion criteria were complete HH[8] of greater than 3 months' duration, no visual neglect (Bells test[20] and Schenkenberg Line Bisection test[21]), and no history of having worn peripheral prism glasses. In addition, participants had corrected monocular visual acuity of at least 20/50 in each eye, refractive error within the −5 diopter (D) to +5 D range, no strabismus, no significant cognitive decline (Short Portable Mental Status Questionnaire[22]), and no balance problems or other deficits that could impair ability to walk or use the prism glasses. Visual field mapping extended to at least 50° from fixation in all directions and was performed using Goldmann perimetry (V4e target), a Humphrey Field Analyzer 120-point full-field screening test, or similar tests, depending on the equipment available at each clinic. To ensure that study inclusion criteria were uniformly applied, screening data were sent to the principal investigator (A.R.B.), who determined eligibility.

Study Design

The study was a double-masked, multicenter crossover trial of real and sham peripheral prism glasses with a counterbalanced AB/BA design (AB = real first; BA = sham first). Each crossover period was 4 weeks. A washout period was not included because no carryover effects were anticipated. To address our secondary goal of providing preliminary comparative data on the oblique and horizontal designs, participants were allocated to receive either real oblique and sham horizontal prism glasses or real horizontal and sham oblique.

At the end of the crossover, a clinical decision whether to continue wearing the real prism glasses was made. For participants who continued, a follow-up telephone interview was conducted approximately 6 months after their final in-office visit (Table 1 and Procedures in the eAppendix in the Supplement).

Treatment Allocation

The clinical coordinator at Schepens assigned participants to 1 of 4 possible treatment allocations (real oblique AB/BA and real horizontal AB/BA) using minimization[23] (Minim software; S. Evans, S. Day, and P. Royston, http://www-users.york.ac.uk/~mb55/guide/minim.html). The first participant was assigned randomly, with each subsequent participant assigned in such a way as to minimize imbalances among the 4 treatment allocations. We could realistically balance for only 2 factors. Study site was the primary factor (because continuation rates varied significantly across sites in our first multicenter study[9]) and side of HH (right or left) was the second factor (because the side of the lesion could potentially affect performance with the prism glasses). We did not balance for age because it was not a significant factor affecting continuation rates in our previous study.[9]

Letter codes, randomly assigned to each of the treatment allocations by a researcher external to the study, were used by the Minim software and in all data records and spreadsheets. There were 2 copies of the code breaker: the first was kept in a sealed envelope in a location known only to the external researcher and the second was sent to Chadwick Optical, Inc so that the correct combinations of prism glasses could be manufactured for each participant. The code was not broken at Schepens until data analyses were completed.

Real and Sham Prism Glasses

The real and sham prism glasses (manufactured by Chadwick Optical, Inc) both comprised an upper and lower rigid Fresnel prism segment with a 12-mm separation[9] embedded in a regular distance-vision spectacle lens in front of the eye on the side of the HH. They differed only in the design (horizontal vs oblique) and the prism power: 57Δ for the real prisms (Figure 1A and B) and 5Δ for the sham prisms (Figure 1C). An extra optical element included with the sham prisms provided visual acuity reduction and chromatic dispersion similar to those experienced with the 57Δ prisms and also reduced the prism power by about 2Δ from the original 5Δ. Hence, the sham prisms provided no useful field expansion (<2°). For the horizontal design, the prisms were base out. For the oblique design, the upper prism was placed base out and down and the lower prism was placed base out and up, with the base-apex line at an angle of tilt of 25° to the horizontal (Figure 1C).

Masking

Double-masking was used, with participants and data collectors being masked as far as possible. In addition, the principal investigator (A.R.B.) who conducted data analyses was masked. However, it was impossible to mask all study personnel; there was an unmasked practitioner at each site who fitted the prism glasses and dealt with clinical aspects of patient care.

Participants were informed that they were evaluating 2 different designs of prism glasses; they were not told that 1 pair was a sham. If they asked about the difference, the practitioner commented on the physical difference of the vertical vs tilted grooves on the Fresnel prism inserts for the horizontal and oblique designs, respectively. To prevent investigator bias, the data collector at each site was unaware of the treatment allocation and the study glasses were retained by the (unmasked) practitioner while the questionnaires were administered. Patients never had possession of both pairs together.

Primary Outcome Measure

At the end of each crossover period, participants were asked a yes/no question: "If the study were to end today, would you want to continue with these prism glasses (ie, the prism glasses worn in that period)?" Our primary outcome was the overall difference, across the 2 periods of the crossover, between the proportion of participants saying yes to real glasses and the proportion saying yes to sham glasses.

Secondary Outcome Measure

Perceived difficulties with mobility were quantified using a 5-point rating scale (no difficulty to extreme difficulty) for 7 situations (items) relevant to HH, including at home, in stores, outdoors, in unfamiliar areas, in familiar areas, in crowded areas, and noticing objects off to the side when walking.[8,24] The questionnaire was administered at baseline (without prisms) and after each period of the crossover. Interval scale measures[25] of perceived difficulty with overall mobility for each participant were estimated using Rasch analysis of the responses to all 7 items (WINSTEPS software, version 3.70.0.2[26]). Rasch measures were expressed as logits (log odds ratios). Mobility improvement scores for real and sham prisms were defined as the difference in perceived difficulty relative to baseline (in logits). Psychometric properties of the questionnaire were good (eTable 2 in the eAppendix in the Supplement).

Comparison Questionnaire

At the end of the crossover, participants completed a comparison questionnaire about the 2 pairs of glasses. They did not have access to the glasses while answering the questions and the questionnaire was administered before they were told that one pair was a sham (debriefing came later [Procedures in the eAppendix in the Supplement]). Questions included: "Which pair would you select (first pair, second pair, or neither)?" "Which pair was better for obstacle avoidance when walking?" "Which pair gave more comfortable vision?" These last 2 questions were scored on a 5-point scale from first pair much better to second pair much better.

Statistical Analyses

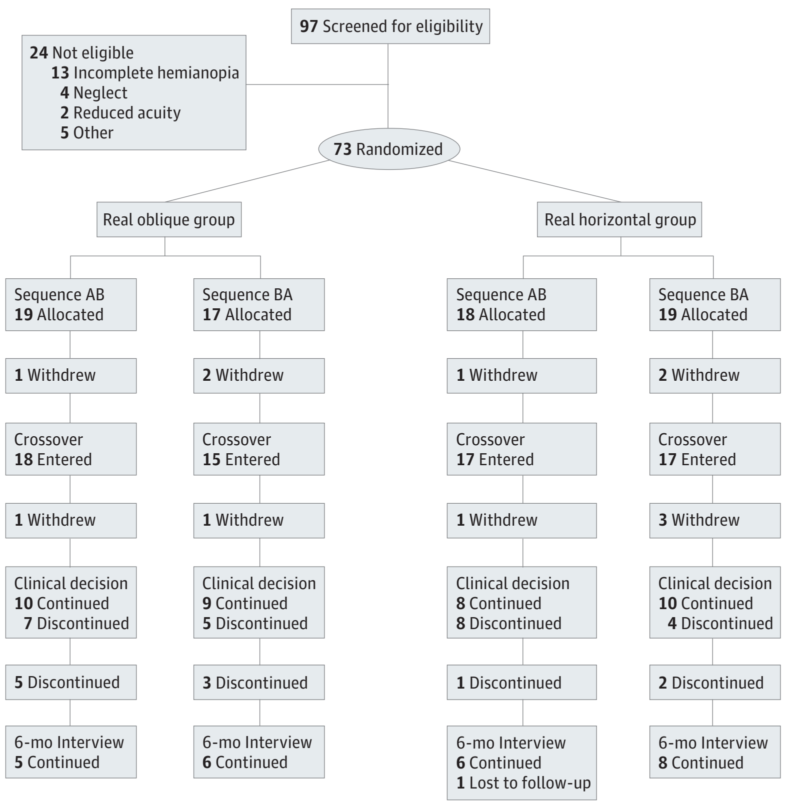
The sample size calculation for the primary outcome measure was based on a McNemar test for a 2 × 2 contingency table of the yes/no responses to real and sham prism glasses for data combined across both periods of the crossover (StudySize software, version 2.0.4; CreoStat HB). In our previous open-label multicenter study,[9] 74% of participants continued with (real) peripheral prism glasses after an initial 4-week trial. We therefore estimated that 70% of participants would say yes to the real prism glasses in this study and that half that number (35%) would say yes to the sham prism glasses. For a 2-tailed test, the minimum sample size to detect a 35% difference in yes responses to real and sham prism glasses was 57 participants, assuming 30% overlap (ie, 30% said yes to both pairs of glasses), power of 90%, and significance (α) level of 1%. Assuming[9] an attrition rate of 20%, we planned to enroll at least 68 participants.

As planned, the primary outcome measure was analyzed using a McNemar test for data combined across both periods of the crossover. In addition, the proportions of participants saying yes to real and yes to sham prism glasses at the end of each period were compared using a 2-proportion z test. As a secondary measure, the proportion expressing a preference for the real prism glasses at the end of the crossover was analyzed using a binomial confidence interval test.

Mobility improvement scores, the secondary outcome measure, were normally distributed. Our primary analysis was a within-subjects comparison of the crossover differences in mobility scores between real and sham prism glasses, analyzed using a paired t test. In addition, differences in mobility scores between patients wearing real and sham prisms were analyzed for each period of the crossover using an independent-samples t test. In our prior open-label multicenter trial,[9] participants who continued wearing peripheral prism glasses gave significantly higher mobility helpfulness ratings for the glasses than participants who discontinued wear. We therefore conducted subgroup analyses of mobility improvement scores based on final status (continuing wear or discontinued wear) at the 6-month interview.

When questionnaires were administered, patients did not know that one pair of glasses was real and one pair was sham; however, for clarity in reporting of results, participant responses have been converted to real or sham glasses rather than first or second pair. All analyses were 2-sided. An α value ≤.01 was considered to indicate statistical significance for the primary analysis and ≤.05 for the secondary analyses.

Figure 3. Participant Flow Through the Study



Minimization was used to allocate participants to treatment group and sequence: real oblique AB/BA and real horizontal AB/BA (AB = real first; BA = sham first).

Table 2. Number of Participants Responding Yes to Real and Sham Prisms in Each Crossover Period and Across Both Periods

Period	No./Total No. (%)		Odds Ratio (95% CI)	z Test	P Value
	Yes to Real	Yes to Sham			
1[a]	19/33 (58)	13/28 (46)	1.6 (0.6-4.3)	0.87	.39
2[a]	20/28 (71)	9/33 (27)	6.7 (2.2-20.4)	3.44	.001
1 and 2[b]	39/61 (64)	22/61 (36)	5.3 (1.8-21.0)[c]	3.40	.001

[a] Analyzed as if for a parallel-arm trial (2-proportion *z* test).

[b] Matched-pairs analysis for the crossover (McNemar test). See Table 3 for the 2 × 2 contingency table.

[c] Marginal odds ratio based on discordant pairs.

Results

Seventy-three patients were enrolled, with 36 allocated to the real oblique group and 37 to the real horizontal group (**Figure 3**). Twelve participants subsequently withdrew: 6 before the start of the crossover (3 because of transportation problems and 3 for no reason) and 6 more during the crossover (3 for health reasons, 1 for visual field recovery, 1 because of transportation problems, and 1 for no reason). Thus, 61 participants (66% male) with a median age of 58 years (range, 18-89 years) completed the crossover; 64% had left hemianopia. The median time since onset was 18 months (range, 3-396 months), with stroke the predominant cause (77%).

At the end of the crossover, 61% (19 of 31) continued prism wear in the oblique group and 60% (18 of 30) in the horizontal group ($P = .92$). At the long-term interview, 36% (11 of 31) and 47% (14 of 30) were still wearing the prism glasses in each group, respectively ($P = .32$). Thus, the overall continuation rate at 6 months was 41% (25 of 61).

In agreement with our prediction, there were no statistically significant differences between the oblique and horizontal groups for any of the outcome measures (eTable 3 in the eAppendix in the Supplement); therefore, data were pooled across the 2 groups for the main analyses reported later. Additional analyses are summarized in the eAppendix Results section in the Supplement, including a summary of reported difficulties with real and sham prism glasses; reasons for discontinuing wear; predictors of long-term wear; and debriefing data.

Primary Outcome Measure

In response to the question "would you want to continue with these prism glasses," the difference between the proportions of participants who said yes to real and yes to sham at the end of the first crossover period was not significant ($P = .39$) but was highly significant at the end of the second period ($P = .001$)

Table 3. Matched Pairs (2 × 2) Classification of the Number of Participants Responding Yes or No to Real and Sham Prism Glasses for Data Combined Across the 2 Periods of the Crossover

		Sham		
		Yes	No	Total
Real	Yes	18	21	39
	No	4	18	22
	Total	22	39	61

Table 4. Mobility Improvement Scores (in Logits) for Each Crossover Period and Across Both Periods

Period	Mean (SD) Real	Mean (SD) Sham	Difference Mean (SD) [95% CI]	*t* Test (2-Tailed)	*P* Value
1[a]	1.9 (3.3)[b] (n = 33)	1.2 (2.2)[b] (n = 28)	0.7 (2.9) [−0.8 to 2.1]	t_{59} = 0.88	.38
2[a]	2.0 (3.4)[b] (n = 28)	1.4 (2.8)[b] (n = 33)	0.6 (3.1) [−2.1 to 1.1]	t_{59} = 0.69	.50
1 and 2 (All participants)[c]	1.9 (3.3) (n = 61)	1.3 (2.5) (n = 61)	0.6 (2.6) [−0.1 to 1.3]	t_{60} = 1.73	.09
1 and 2 (Continued wear)[c]	3.0 (3.2) (n = 25)	1.1 (2.4) (n = 25)	1.9 (2.7) [0.7 to 3.0]	t_{24} = 3.45	.002
1 and 2 (Discontinued wear)[c]	1.1 (3.3) (n = 35)	1.6 (2.7) (n = 35)	−0.5 (2.1) [−1.2 to 0.3]	t_{34} = 1.29	.21

[a] Analyzed as if for a parallel-arm trial (independent-samples *t* test).

[b] Mobility improvement scores all significantly different from 0.0 (1-sample *t* tests, all *P* < .01).

[c] Matched-pairs analysis for the crossover (paired *t* test).

(**Table 2**). For data combined across the 2 periods of the crossover, the overall proportion of participants who said yes to the real prism glasses (64% [39 of 61]) was higher than the overall proportion saying yes to the sham prism glasses (36% [22 of 61]) (Table 2 and **Table 3**). The 28% difference in these proportions, the primary outcome, was significant (95% CI, 12%-42%; McNemar test *P* = .001) (Table 2 and Table 3).

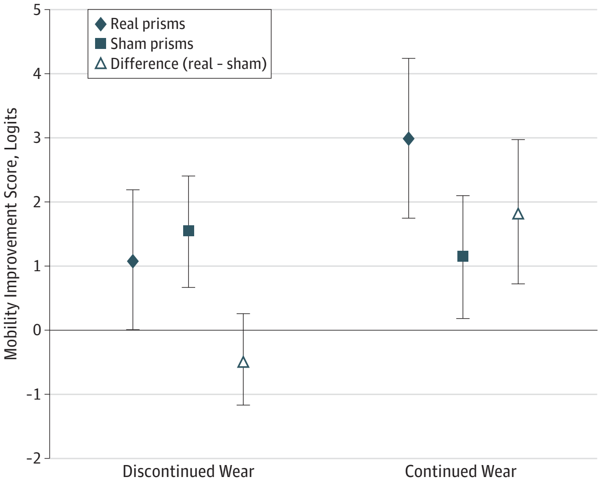
Overall Mobility Improvement Score

Relative to baseline, there was a significant improvement in the overall mobility score for both real and sham prism glasses in both crossover periods (*P* < .01) (**Table 4**). However, the difference in the amount of improvement between participants wearing real and sham prism glasses was not significant in either period (*P* = .38 and .50, respectively) (Table 4). In contrast, analysis of the within-subjects crossover differences revealed a trend toward greater improvement with the real than the sham prisms (*P* = .09) (Table 4). Subgroup analyses further revealed that participants who continued with prism glasses at the 6-month follow-up reported markedly more improvement for real than sham prisms at the end of the crossover (*P* = .002), whereas participants who discontinued wear reported little difference in the amount of perceived improvement for the 2 pairs of glasses (Table 4 and **Figure 4**).

Comparison Questionnaire

When asked which pair of glasses they would select at the end of the crossover, 61% (37 of 61) chose the real prism glasses; 26% (16 of 61), the sham glasses; and 13% (8 of 61), neither pair. The number of participants selecting real prism glasses approached significance when expressed as a proportion of the total number completing the crossover (61%; 95% CI, 48%-72%; *P* = .07) and was significant when expressed as a proportion of those who actually stated a preference (70% [37 of 53]; 95% CI, 56%-80%; *P* = .01). These results support the findings of the primary outcome measure.

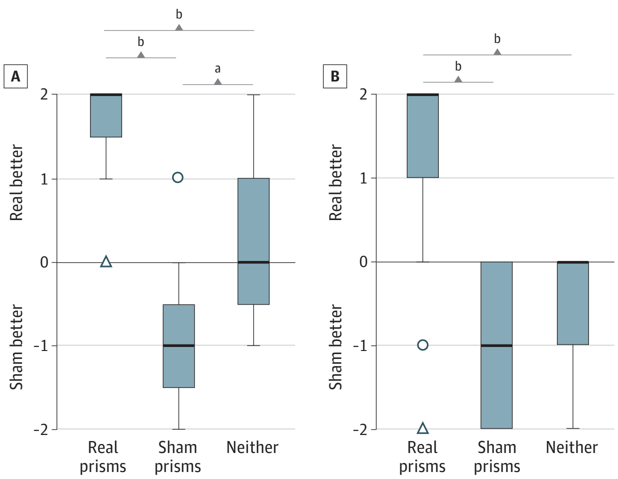
Figure 4. Mean Mobility Improvement Scores for Real and Sham Prism Glasses



Participants who continued prism wear reported significantly more improvement with real than sham glasses. Mobility scores are in logit units; more positive values represent greater improvement. For real and sham prisms, error bars are 95% confidence intervals of the mean scores. For the difference between real and sham, errors bars are 95% confidence intervals of the mean paired differences.

Participants who selected real prism glasses rated them as much better for obstacle avoidance and vision comfort than sham prism glasses (median ratings) (**Figure 5**). By comparison, participants who selected sham prism glasses rated them as only slightly better than real prism glasses for obstacle avoidance and vision comfort (median ratings) (Figure 5). Participants who selected neither pair of glasses gave a median rating of "no difference" for both these aspects. In a similar vein, the main reason given for selecting real prism glasses was that

Figure 5. Median Relative Ratings of Real and Sham Prism Glasses From the Comparison Questionnaire



Ratings for obstacle avoidance (A) and ratings for vision comfort (B), grouped by whether participants selected real prism glasses (n = 37), sham prism glasses (n = 16), or neither pair of prism glasses (n = 8). Responses of participants who selected real prism glasses were significantly different from those who selected sham or neither. Participants who selected real prism glasses rated them as much better than the sham, whereas those who selected sham glasses rated them as only slightly better than the real glasses. (Participants, still masked when this questionnaire was administered, gave rankings in terms of first pair or second pair, which were subsequently converted to real or sham. Scale: −2 = sham much better; −1 = sham slightly better; 0 = no difference; 1 = real slightly better; 2 = real much better). The thick horizontal line within each box is the median; box length is the interquartile range (IQR); whiskers represent the range of the data within 1.5 × IQR; open circle indicates outlier within 1.5× to 3 × IQR; and open triangle indicates far outlier beyond 3 × IQR.

[a] P = .01.

[b] P = .001.

they were the pair of glasses that was more helpful when walking (92% [34 of 37]), whereas the main reasons for selecting sham prism glasses were that they were the pair with which vision was more comfortable (81% [13 of 16]) and with which fewer difficulties had been encountered.

Discussion

Participants demonstrated a preference for real peripheral prism glasses over sham peripheral prism glasses. They were about 5 times more likely to say yes only to real prism glasses than yes only to sham prism glasses during the crossover (Table 2) (marginal odds ratio, 5.3), and 64% selected real prisms over sham prisms at the end of the crossover. Moreover, real prism glasses were rated as much more helpful than the sham for obstacle avoidance when walking. The proportion of participants who continued with real prism glasses was similar for the horizontal and oblique designs, suggesting that both designs were helpful for everyday pedestrian mobility. However, a preference for the oblique design might be expected for driving.[19]

The participants in this study were patients with complete HH without spatial neglect and without significant cognitive decline attending a range of hospital, university, and private practice clinics. As such, we believe the results to be highly generalizable to clinical rehabilitation of patients with similar characteristics. Furthermore, all procedures and data collection methods were based on current clinical practice.

Our results demonstrate the importance of including a control condition when evaluating a rehabilitation intervention. Specifically, 26% of participants selected the sham prism glasses at the end of the crossover. The reasons for their choice were related to vision comfort and lack of difficulties in using the glasses rather than improved functional performance. These are patients who in an open-label trial might artificially inflate success rates when only a short-term follow-up is included (eg, 1 month) because they would like to continue with the study intervention but for the wrong reasons and would likely discontinue use of the device before a longer-term follow-up (eg, 6 months). Indeed, the short-term success rate (continuation rate at the end of the crossover) was lower in this controlled trial than in our prior open-label trial[9] of the peripheral prism glasses (61% vs 74%), while long-term success rates were more similar (41% vs 47%). Furthermore, placebo effects were evident in the self-ratings of mobility difficulties; participants reported an improvement in overall mobility for both sham and real prism glasses. However, for participants who continued to wear prism glasses in the long term, the improvement was greater for the real than the sham glasses. Thus, for this subgroup, we were able to measure both treatment and placebo effects.

Although not a goal of this study, we evaluated the ability of a range of factors to predict long-term success (continuation rates) (eTable 6 in the eAppendix in the Supplement). The strongest predictors were participants' responses to the prism glasses at the end of the crossover. Unsurprisingly, those who said yes to real prism glasses, those who rated them as better than the sham for obstacle avoidance, and those who did not report any difficulties with them were more likely to continue wearing prism glasses in the long term. By comparison, age was only a weak predictor, and side and duration of hemianopia were not predictive (consistent with our prior open-label trial[9]). Difficulty interpreting the prism image was a major reason for discontinuing wear (eFigure and eTable 5 in the eAppendix in the Supplement). Limited training in how to use the prism glasses was provided, similar to that implemented in our prior study; however, it is possible that some participants might have benefited from more extensive training. We are currently evaluating the effects of intensive computer-based training for use of the peripheral prism glasses.[27]

In planning this study, our aim was to achieve a robust but practical design that would fit within a busy clinic schedule; however, some limitations need to be considered. Differing numbers of participants were recruited at each clinic and we were unable to ensure total masking of data collectors. Furthermore, our outcome measures were based on patient preference and self-report questionnaires. For practical reasons, evaluations of functional mobility performance, such as those used in laboratory-based studies of devices for visual field loss,[28-30] could not be used.

Our primary outcome measure was limited by period effects. Specifically, after the first crossover period, the difference in the proportion of participants saying yes to real and sham prism glasses was only 12%, compared with 44% after the second period. While responses at the end of the first period might have been affected by the knowledge that another pair of glasses was to be worn in the second period, responses at the end of the second period were clearly influenced by having already worn either real or sham glasses in the first period. Interestingly, period effects were less evident in the mobility improvement scores because the magnitude of the difference in perceived improvement between those wearing real and sham prism glasses was similar at the end of each period (Table 4).

To evaluate the evidence base for a given treatment or intervention, systematic reviews synthesize data across trials. Combining results from crossover and parallel-arm trials is not easy; various methods have been proposed.[31-33] One straightforward approach is to use data from the first period only, as if from a parallel-arm trial; however, this means that valuable information from the second period may be lost and ignores the fact that the study was designed as a crossover. We suggest that the period effects present in our original primary outcome measure provide an example of a situation in which it would have been potentially misleading to include data from only the first crossover period.

In conclusion, this study addresses the lack of controlled trials identified in recent systematic reviews of interventions for homonymous visual field loss[11-14] and strengthens the evidence base for the efficacy of peripheral prism glasses as a mobility aid for patients with HH. The next step should be a clinical trial with outcome measures evaluating functional performance on real-world or simulated mobility tasks.

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Analysis and interpretation of data: Bowers, Peli.
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Additional Contributions: Doris Apfelbaum, BA, maintained the study database. Practitioners at study sites included Henry A. Greene, OD, Academy Eye Associates, Durham, North Carolina; Susan A. Primo, OD, MPH, Emory Eye Center, Atlanta, Georgia; David Lewerenz, OD, Northeastern State University Oklahoma College of Optometry, Tahlequah; Tracy Matchinski, OD, Illinois Eye Institute, Chicago; Elli Kollbaum, OD, Community Eye Care Center, Indiana University School of Optometry, Bloomington; Barry Kavanaugh, OD, Seven Lakes Eye Care, West End, North Carolina; Dawn K. DeCarlo, OD, MS, MSPH, and Marsha Swanson Snow, OD, UAB Center for Low Vision Rehabilitation, Birmingham, Alabama; Rosalind Creer, PhD, Manchester Royal Eye Hospital Optometry Department, Manchester, England; Paul Levine, OD, Vision Care Specialists, PC, Southborough, Massachusetts; Selma Chin, OD, Vista Center for the Blind and Visually Impaired, Palo Alto, California; Richard (Scott) Hearing, OD, Visual Health, Jupiter Eye Center, Jupiter, Florida; Thomas Whittaker, MS, JD, MD, Departments of Ophthalmology and Neurology, University of Kansas Medical Center, Prairie Village.

REFERENCES

1. Young CA. Homonymous hemianopsia during pregnancy aided by reflecting prism. *Arch Ophthalmol*. 1929;2(5):560-565. doi:10.1001/archopht.1929.00810020581008.

2. Smith JL, Weiner IG, Lucero AJ. Hemianopic Fresnel prisms. *J Clin Neuroophthalmol*. 1982;2(1):19-22.

3. Woo GC, Mandelman T. Fresnel prism therapy for right hemianopia. *Am J Optom Physiol Opt*. 1983;60(8):739-743.

4. Perez AM, Jose RT. The use of Fresnel and ophthalmic prisms with persons with hemianopic visual field loss. *J Vis Impair Blind*. 2003;97(3):173-176.

5. Hedges TR Jr, Stunkard J, Twer A. Fresnel prisms: their value in the rehabilitation of homonymous hemianopsias [in German]. *Klin Monbl Augenheilkd*. 1988;192(5):568-571.

6. Lee AG, Perez AM. Improving awareness of peripheral visual field using sectorial prism. *J Am Optom Assoc*. 1999;70(10):624-628.

7. Peli E. Field expansion for homonymous hemianopia by optically induced peripheral exotropia. *Optom Vis Sci*. 2000;77(9):453-464.

8. Giorgi RG, Woods RL, Peli E. Clinical and laboratory evaluation of peripheral prism glasses for hemianopia. *Optom Vis Sci*. 2009;86(5):492-502.

9. Bowers AR, Keeney K, Peli E. Community-based trial of a peripheral prism visual field expansion device for hemianopia. *Arch Ophthalmol*. 2008;126(5):657-664.

10. O'Neill EC, Connell PP, O'Connor JC, Brady J, Reid I, Logan P. Prism therapy and visual rehabilitation in homonymous visual field loss. *Optom Vis Sci*. 2011;88(2):263-268.

11. Pollock A, Hazelton C, Henderson CA, et al. Interventions for visual field defects in patients with stroke. *Cochrane Database Syst Rev*. 2011;(10):CD008388.

12. Lane AR, Smith DT, Schenk T. Clinical treatment options for patients with homonymous visual field defects. *Clin Ophthalmol*. 2008;2(1):93-102.

13. Pambakian A, Currie J, Kennard C. Rehabilitation strategies for patients with homonymous visual field defects. *J Neuroophthalmol*. 2005;25(2):136-142.

14. Plow EB, Maguire S, Obretenova S, Pascual-Leone A, Merabet LB. Approaches to rehabilitation for visual field defects following brain lesions. *Expert Rev Med Devices*. 2009;6(3):291-305.

15. Rossi PW, Kheyfets S, Reding MJ. Fresnel prisms improve visual perception in stroke patients with homonymous hemianopia or unilateral visual neglect. *Neurology*. 1990;40(10):1597-1599.

16. Gottlieb DD, Freeman P, Williams M. Clinical research and statistical analysis of a visual field awareness system. *J Am Optom Assoc*. 1992;63(8):581-588.

17. Szlyk JP, Seiple W, Stelmack J, McMahon T. Use of prisms for navigation and driving in hemianopic patients. *Ophthalmic Physiol Opt*. 2005;25(2):128-135.

18. Peli E. Peripheral field expansion device. US patent 7,374,284 B2. 2008.

19. Bowers AR, Tant M, Peli E. A pilot evaluation of on-road detection performance by drivers with hemianopia using oblique peripheral prisms. *Stroke Res Treat*. 2012;2012:176806.

20. Vanier M, Gauthier L, Lambert J, et al. Evaluation of left visuospatial neglect: norms and discrimination power of two tests. *Neuropsychology*. 1990;4(2):87-96. doi:10.1037//0894-4105.4.2.87.

21. Schenkenberg T, Bradford DC, Ajax ET. Line bisection and unilateral visual neglect in patients with neurologic impairment. *Neurology*. 1980;30(5):509-517.

22. Pfeiffer E. A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. *J Am Geriatr Soc*. 1975;23(10):433-441.

23. Altman DG. *Practical Statistics for Medical Research.* London, England: Chapman and Hall; 1991.

24. Turano KA, Geruschat DR, Stahl JW, Massof RW. Perceived visual ability for independent mobility in persons with retinitis pigmentosa. *Invest Ophthalmol Vis Sci*. 1999;40(5):865-877.

25. Massof RW, Rubin GS. Visual function assessment questionnaires. *Surv Ophthalmol*. 2001;45(6):531-548.

26. Linacre JM. *WINSTEPS* [computer program]. Version 30.70.02. Beaverton, OR: Winsteps.com; 2010.

27. Houston K, Churchill J, Wiegand J, et al. Perceptual-motor adaptation in hemianopes wearing peripheral prisms is possible: preliminary results [abstract]. *Invest Ophthalmol Vis Sci*. 2013;54:2759.

28. Bowers AR, Mandel AJ, Goldstein RB, Peli E. Driving with hemianopia, I: detection performance in a driving simulator. *Invest Ophthalmol Vis Sci*. 2009;50(11):5137-5147.

29. Bowers AR, Luo G, Rensing NM, Peli E. Evaluation of a prototype Minified Augmented-View device for patients with impaired night vision. *Ophthalmic Physiol Opt*. 2004;24(4):296-312.

30. Luo G, Woods RL, Peli E. Collision judgment when using an augmented-vision head-mounted display device. *Invest Ophthalmol Vis Sci*. 2009;50(9):4509-4515.

31. Higgins JPT, Green S, eds. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0. http://handbook.cochrane.org/. Updated March 2011. Accessed April 22, 2013.

32. Elbourne DR, Altman DG, Higgins JPT, Curtin F, Worthington HV, Vail A. Meta-analyses involving cross-over trials: methodological issues. *Int J Epidemiol*. 2002;31(1):140-149.

33. Stedman MR, Curtin F, Elbourne DR, Kesselheim AS, Brookhart MA. Meta-analyses involving cross-over trials: methodological issues. *Int J Epidemiol*. 2011;40(6):1732-1734.

Supplementary Online Content

Bowers AR, Keeney K, Peli E. Randomized crossover clinical trial of real and sham peripheral prism glasses for hemianopia. *JAMA Ophthalmol*. Published online November 7, 2013. doi:10.1001/jamaophthalmol.2013.5636.

eAppendix. Procedures, Rasch Analysis of Mobility Questionnaire, Results, eTables, and eFigure.

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix Table of Contents

eTable 1: Summary of previous controlled trials of prismatic corrections for hemianopia

Study	n	Description	Findings	Limitations
Rossi (1990)	39	• Parallel arm study comparing treatment to no treatment group; • Treatment group received 15Δ bilateral yoked sector press-on Fresnel prisms base toward the affected side, fitted 2mm into the blind hemifield; • Follow up at 2 and 4 weeks; • Patients had either hemianopia or spatial neglect.	• At 4 weeks the treatment group performed better than the control group on neglect tests (line bisection and cancellation); • However, there were no significant between-group differences in the amount of improvement on the Barthel ADL-mobility score • Field "expansion" found in both the treatment and control groups	• Study performed in an in-patient stroke rehabilitation unit within the period when spontaneous visual field recovery and spontaneous neglect recovery could occur (enrolled on average within 5 weeks of the stroke); • As the prisms were fitted 2mm into the blind hemifield, they should have had no effect on the perimetry results (the eye is in primary gaze for perimetry), thus the improvements in visual field that were recorded were most likely due to spontaneous recovery. • Data collectors were unmasked for the majority of outcome measures; • At the follow ups, the treatment group were only tested with prisms and the no-treatment group were only tested without prisms; • The extent to which participants with hemianopia had complete or incomplete hemianopia at baseline is unclear
Gottlieb (1992)	34	• Non-randomized crossover comparing Gottlieb 18.5Δ unilateral sector ophthalmic ground-in prism button to a control device, which appeared similar but included a "plano lens without prism power"; • Wore each device for 2 weeks; • Patients had hemianopia either with or without spatial neglect.	• Ratings of device 'effectiveness' for mobility and localization were higher for the real than the sham prisms. • All participants rejected the sham device. • 19 still using the prism glasses after 18 months.	• Unclear whether all participants received both real and sham glasses; • Lack of clarity in recruitment methods and study locations: "initial" phase (n = 8), "replication" phase (n = 16), and patients (n = 10) "added to the experimental population by the primary investigator" • Real prisms always received before sham prisms; • Included people with hemianopia with and without visual neglect; • Potential for bias as unclear who administered the questionnaire, and no details were reported about whether the person administering the response questionnaire was masked or whether the patients were masked; • No information provided on prism placement. • Unclear who funded the study and whether participants had to pay for the prism glasses
Szylk (2005)	10	• Randomized crossover comparing Gottlieb style unilateral sector prisms in two designs (a) 18.5Δ ophthalmic ground-in prism (b) 20Δ press-on Fresnel prism;. • Three months of training with each type of lens; • Patients had hemianopia.	• No difference in performance with ophthalmic prism and press-on prism on a large test battery (lab tests, mobility tests, driving simulator and on-road driving); • 6 still using the prism glasses after 2 years.	• Performance on lab, mobility and driving tasks were pooled together in general categories; the effects on specific aspects of mobility or driving were not reported; • Study provided a comparison between two prismatic lenses where the only difference was in cosmetic appearance and image quality, but not in field expansion; thus a performance difference was not really expected. • As the study did not include a no-treatment control group, or a no-training control group, there is no information about the effects of the prismatic correction alone or the effects of the training alone • No information about whether patients were screened to exclude neglect

Rossi PW, Kheyfets S, Reding MJ. (1990) Fresnel prisms improve visual perception in stroke patients with homonymous hemianopia or unilateral visual neglect. Neurology. 40:1597-1599.
Gottlieb DD, Freeman P, Williams M. (1992) Clinical research and statistical analysis of a visual field awareness system. J Am Optom Assoc. 63:581-588.
Szlyk JP, Seiple W, Stelmack J, McMahon T. (2005) Use of prisms for navigation and driving in hemianopic patients. Ophthalmic Physiol Opt. 25:128-135.

Procedures

Each site was provided with detailed written protocols and data record sheets. After each participant contact, whether by phone or in-office visit, data sheets were sent to Schepens for review. Monitoring the data in this way ensured adherence to the protocols and that all participants were treated equally.

Screening tests, the baseline mobility questionnaire and measurements for prism glasses were conducted at the first visit. Presbyopic participants were given the option of a small bifocal segment below the lower prism segment, sufficient for short duration spot reading. Study frames (from a small selection) and lenses were provided free of charge to all participants.

For each participant who met the study criteria, Chadwick Optical, Inc. (White River Junction, Vermont) manufactured a pair of real and sham prism glasses. To ensure that participants received the glasses in the correct order, only the first pair was mailed to the practitioner for collection by the patient at visit two. Once the first pair was dispensed, the practitioner informed Chadwick Optical and the second pair was then mailed to the practitioner in time for collection by the patient at visit three. At visit three, the first pair was retained by the practitioner before the second pair was fitted. Thus the patient never had access to both pairs of glasses at the same time.

Training in how to use the prism glasses was conducted by the practitioner at visit two. As the first pair was a sham for half of the participants, training in how to use the glasses (Bowers et al., 2008) was conducted using real upper and lower horizontal peripheral prism segments mounted on a clip placed over the participant's habitual spectacles. Participants were taught to view through the central prism-free area of the spectacle lens at all times and to turn the head and eyes to fixate objects of interest that were initially detected from the prism image in peripheral vision. A simple "reach and touch" training exercise was used to familiarize participants with the relationship between the apparent and real positions of objects detected from the prism image; this exercise was also encouraged for home-training. Participants were given verbal and written instructions about how to use the prism glasses and were encouraged to wear them as much as possible each day. They were advised not to use the peripheral prism glasses for driving or prolonged reading.

After wearing the first pair of prism glasses for four weeks, the participant returned for the third visit (end of first period of crossover). After the practitioner retained the first pair of glasses, the data collector asked the question "If the study were to end today, would you want to continue with these prism glasses (i.e. the prism glasses worn in the first period)?", and also administered the mobility questionnaire for the first pair. The practitioner then fitted the second pair of glasses.

Four weeks later at the fourth visit (end of second period of crossover), the practitioner retained the second pair, the data collector then determined whether the participant would want to continue with the second pair and administered the mobility questionnaire for the second pair followed by the comparison questionnaire. After the questionnaires, the practitioner "debriefed" the participant and explained that one pair of glasses was a sham. A clinical decision whether or not to continue prism wear was then made. The criteria to continue wear were: the real prism glasses were helpful for mobility, the participant wanted to continue wear and the practitioner deemed that it was clinically appropriate. Participants were not allowed to keep sham prism glasses, even if they indicated a preference for the sham glasses.

For participants who continued to wear prism glasses, a telephone follow-up interview was conducted approximately 6 months after their final in-office visit (median 6.0 months, interquartile range 5.8 to 6.9). In our first multicenter study, the long-term follow up was at 12 months; however the majority of participants who discontinued wearing prism glasses after the clinical decision to continue did so within 3 months. Hence we selected 6 rather than 12 months for the long-term follow up for this study.

Reference

Bowers AR, Keeney K, Peli E. (2008) Community-based trial of peripheral prism visual field expansion device for hemianopia. Arch Ophthalmol.126:657-664.

Rasch Analysis of Mobility Questionnaire

Rasch analysis (Winsteps software, version 3.70.0.2) confirmed that the psychometric properties of the mobility questionnaire were good (eTable 2).

eTable 2

Summary statistics from Rasch analysis of ratings of perceived difficulty with mobility

Parameter	Mean Rasch measure[1]	Separation index[2]	Separation reliability[3]	Mean infit mean square[4]
Person ability	-0.11 ± 2.08	2.67	0.88	0.99
Item difficulty	0.00 ± 1.38	6.36	0.98	0.99

[1] Mean person ability measure near 0 indicates good targeting of a questionnaire; Mean item difficulty is always set to 0.
[2] Separation indices indicate how well the questionnaire differentiates between persons and items; the greater the index, the better the separation.
[3] Person and item separation reliability values > 0.8 are acceptable (Pesudovs et al., 2007).
[4] The model expectation for item infit mean square is 1.

References
Linacre JM. (2010). WINSTEPS® (Version 30.70.02) Rasch measurement computer program. Beaverton, Oregon: Winsteps.com.
Pesudovs K, Burr JM, Harley C, Elliott DB. (2007) The development, assessment, and selection of questionnaires. Optom Vis Sci. 84:663-674.

Results

Oblique group versus horizontal group

In terms of baseline characteristics, there were no significant differences between the oblique and horizontal groups in the proportion of participants with left hemianopia (as planned) and the level of perceived difficulty with mobility at baseline (eTable 3). However, there was a trend for the oblique group to be older than the horizontal group and to have a higher proportion of participants with stroke as the primary cause of the hemianopia (eTable 3).

The pattern of responses to the question "would you want to continue with these prism glasses?" (asked after each period of the crossover) was similar for the two groups (eTable 4**).** Across the two periods of the crossover, 65% said yes to real prism glasses in the oblique group and 32% said yes to sham glasses, compared with 63% and 40% in the horizontal group, respectively. Furthermore, the mobility improvement scores for the real prism glasses were not significantly different for the two groups, and there were no significant differences in the proportions of participants that continued wear at the end of the crossover (eTable 3).

The long-term follow up results possibly suggest that continuation rates were higher in the horizontal than the oblique group (eTable 3). However, the data need to be interpreted with caution. The long-term follow up was primarily for informational purposes; the study was not designed to have sufficient sample size and power to support between-group analyses at that time point.

eTable 3: Comparison of oblique and horizontal groups including all participants who completed the crossover (n = 61)

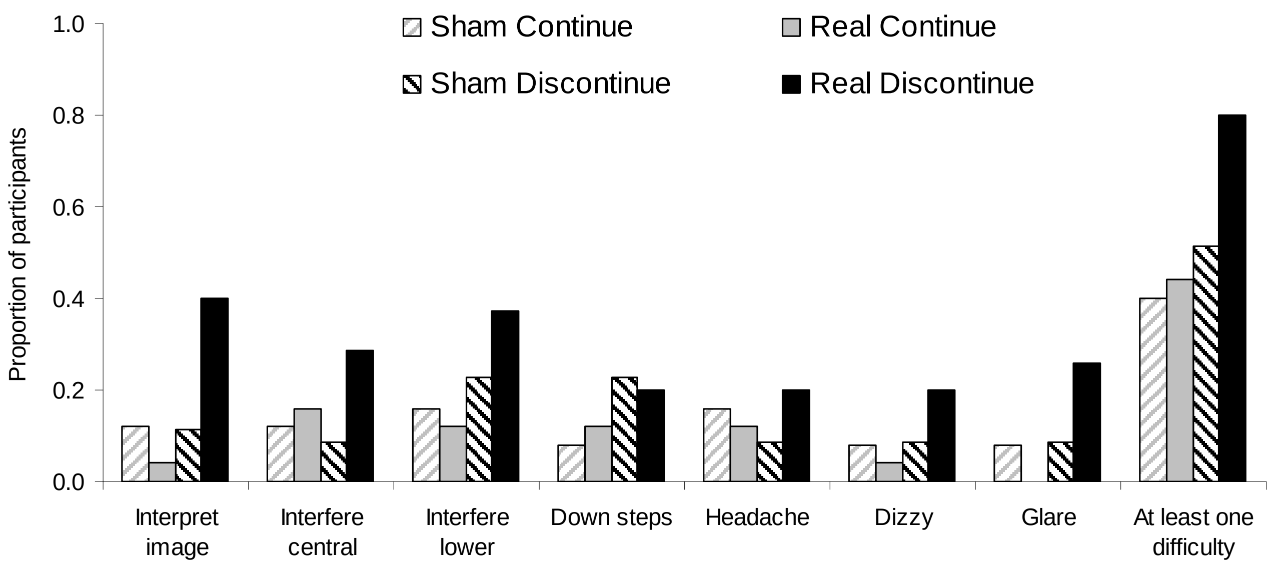
	Oblique group (n = 31)	**Horizontal group (n = 30)**	**Test for between group difference**
Age, Median (IQR)	64 (53 to 69)	56 (46 to 63)	z = 1.746, p = 0.081
Male, n (%)	23 (74)	17 (57)	χ^2 = 2.075; p = 0.150
Left hemianopia, n (%)	21 (68)	18 (60)	χ^2 = 0.396; p = 0.529
Hemianopia caused by stroke, n (%)	28 (90)	19 (63)	χ^2 = 6.280; **p = 0.012**
Time since onset, median (IQR), mo	12 (7 to 36)	36 (11 to 63)	z = 1.584, p = 0.113
Overall baseline mobility difficulty Mean (SD), logits	-0.17 (2.31)	-0.06 (1.89)	t = 0.196, p = 0.845
Clinical decision to continue wear at end of crossover, n (%)	19 (61)	18 (60)	χ^2 = 0.011, p = 0.918
Continued wear long term, n (%)	11 (36%)	14 (47%)	χ^2 = 1.009, p = 0.315
Overall improvement in mobility with real prism glasses, Mean (SD) logits	1.70 (3.51)	2.19 (3.15)	t = 0.574, p = 0.568

eTable 4: 2 × 2 classification of the number (%) of participants saying "yes" to real and sham prism glasses in the oblique and horizontal groups, data combined across the two periods of the crossover.

Oblique group	Sham				Horizontal group	Sham			
		Yes	No	Total			Yes	No	Total
Real	Yes	8 (26)	12 (39)	20 (65)	Real	Yes	10 (33)	9 (30)	19 (63)
	No	2 (7)	9 (29)	11 (35)		No	2 (7)	9 (30)	11 (37)
	Total	10 (32)	21 (68)	31 (100)		Total	12 (40)	18 (60)	30 (100)

Reported difficulties for real and sham prism glasses

For participants who continued prism wear, the proportion reporting at least one difficulty with the prisms was similar for real and sham prism glasses (44% and 40%, respectively; eFigure). However, for participants who discontinued prism wear, the proportion reporting at least one difficulty was significantly higher for the real prism glasses (80% and 51%, respectively; $p = 0.013$; eFigure). In particular, they reported more difficulties with interpreting the prism image and interference in central vision (eFigure). Similarly, a higher proportion of those who discontinued than continued reported at least one difficulty with real prism glasses (eFigure – *compare solid gray and black columns*). By comparison, for sham prism glasses, there were no such differences between those who discontinued and continued (eFigure - *compare hatched columns*).



eFigure: Proportion of participants reporting difficulties with real and sham prism glasses.
Those who discontinued were more likely to report difficulties with real than sham prism glasses (compare black solid and black hatched columns) and were more likely to report difficulties with real prism glasses than those who continued (compare black solid and gray solid columns)

Reasons for continuing and discontinuing prism wear
The main reason for continuing wear in the long term was that the prisms were helpful for noticing and avoiding obstacles when walking (24/25; 96%). The main reasons for discontinuing wear are summarized in eTable 5.

eTable 5: Main reasons for discontinuing prism wear

	All discontinued (n = 35)
Not helpful for detecting objects / not helpful for mobility, n (%)	23 (66)
Difficulty interpreting image, n (%)	23 (66)
Not motivated, n (%)	18 (51)
Headaches, n (%)	5 (14)

Each patient answered yes or no to each of the reasons

Debriefing
In the debriefing, 61% (37/61) of participants reported that they thought that one pair of glasses might have been a sham; of these, 92% (34/37) correctly identified the sham. The main reason given was that the sham pair did not provide any useful field expansion ("no help", "did not work", "could not see things from the side").

Predicting long-term success rates
Using ROC analyses, we evaluated predictors of long-term success rates, deriving the area under the curve (AUC) for each predictor. As might be expected, a positive response to the question "would you want to continue with these [real] prism glasses?" was the strongest predictor of long-term continuation rates (eTable 6). This was closely followed by other measures related to the participant's experiences of using the prism glasses, including ratings of real prisms relative to sham prisms, and reports of at least one difficulty with the real prism glasses (eTable 6). By comparison, age was only a weak predictor, and side and duration of hemianopia were not predictive. Importantly, neither group (real oblique or real horizontal) nor sequence (real first or sham first) were significant predictors (eTable 6).

eTable 6. Summary of ROC analyses for individual predictors of whether or not participants continued to use prism glasses in the long-term.

	AUC[a]	95% CI	Best Threshold	Specificity	Sensitivity	OR	95% CI	p-value	More likely to continue if…
Demographics									
Age	0.64	0.50 - 0.78	64	0.49	0.84	0.96	0.93 - 1.00	**0.05**	Younger
Gender	0.56	0.44 - 0.68		0.40	0.72	1.71	0.57 - 5.17	0.34	
Vision									
Side of hemianopia	0.56	0.44 - 0.69		0.69	0.44	0.58	0.20 - 1.69	0.32	
Duration of condition[b]	0.51	0.34 - 0.64	28	0.63	0.52	1.00	0.99 - 1.01	0.93	
Ratings of real prisms									
"Yes" to real[c]	0.78	0.69 - 0.87		0.60	0.96	36.00	4.36 - 297.36	**0.001**	Said yes to real prisms
Obstacle avoidance relative to shams[c]	0.77	0.66 - 0.88	0.5	0.57	0.88	2.63	1.49 - 4.63	**0.001**	Rated real as better than sham
Vision comfort relative to shams[d]	0.70	0.57 - 0.83	1.5	0.77	0.60	1.74	1.16 - 2.60	**0.01**	Rated real as better than sham
Overall mobility improvement [e]	0.64	0.50 - 0.78	0.5	0.49	0.88	1.21	1.01 - 1.45	**0.04**	Mobility improvement with real prism
At least one difficulty with real prisms	0.68	0.56 - 0.80		0.80	0.56	0.20	0.06 - 0.62	**0.01**	Did not report any difficulty
Study factors									
Sequence (real or sham first)	0.58	0.45 - 0.71		0.60	0.56	0.52	0.18 - 1.48	0.22	
Group (oblique or horizontal)	0.57	0.44 - 0.69		0.57	0.56	1.70	0.60 - 4.78	0.32	

[a] Area under the curve
[b] Reported in months
[c] "If the study were to end today, would you want to continue with these prism glasses".
[d] Rating from comparison questionnaire (-2 = Sham much better to 2 = Real much better).
[e] Reported in logit units; Positive values indicate improved mobility with real prisms (lower levels of perceived difficulty)