

Community-Based Trial of Peripheral Prism Visual Field Expansion Device for Hemianopia

Fitting and Training Protocol

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Peripheral Prisms for Hemianopia Study

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Note: As an adjunct to this protocol, please read the Peli (2000) article referenced at the end of this document. It is included with the set of papers provided to you for this study and is also available to download from the Recent Papers section of Peli's website at: <http://www.eri.harvard.edu/faculty/peli/index.html>

Overall goal of prism fitting

The overall goal of the prism fitting is to determine the lowest position at which the upper prism can be worn and the highest position at which the lower prism can be worn i.e., to fit the prisms as close together as possible while still allowing comfortable central vision and a natural head posture when walking. In order to achieve this goal, the protocol lays out a standardized procedure for fitting, adjusting and evaluating the position of the upper prism segment and then the lower prism segment.

General fitting instructions

1. Patients will be fitted with the peripheral prisms when they meet the subject criteria described in the "step-by-step outline" of study document.
2. The peripheral prisms will be 40^A Press-On™ Fresnel prisms (3M Health Care, St Paul, MN) provided and precut along one edge by Chadwick Optical, Inc.
3. The peripheral prisms will be fitted to one lens of spectacles worn primarily for distance vision (see spectacle requirements below)
4. The peripheral prisms will be fitted to the spectacle lens on the side of the hemianopia (i.e. on the right lens for right hemianopia).
5. The peripheral prisms will be applied to the spectacle lens to provide base out prismatic effect.
6. The smooth surface of the Fresnel prism will be applied to the inner surface (i.e. the surface closer to the eye) of the spectacle lens.

Spectacle requirements

The peripheral prisms will be fitted to one lens of spectacles worn primarily for distance vision - patients must obtain, or have a suitable pair of spectacles prior to prism fitting. If subjects do not have suitable spectacles, Chadwick Optical will provide basic eyewear (limited choice of frames and ophthalmic lenses to ensure best corrected vision) free of charge. Add-ons such as Transitions or progressives will need to be absorbed by another source.

1. In order to allow sufficient height for fitting the peripheral prisms, the "B" (vertical) dimension of the spectacle frame should be $\geq 35\text{mm}$ with **at least 10mm** from the pupil center to the top edge of the frame. It is very important to ensure that there is adequate distance above the pupil center for the upper prism. If the current spectacles

do not have sufficient height, Chadwick Optical will provide appropriate spectacles (as described below) with sufficient height.

2. If the patient wears single-vision distance spectacles, fit the peripheral prisms to these.
3. If the patient wears multifocal or bifocal spectacles, fit the peripheral prisms to these, but cut a small section out of the bottom of the lower prism segment (see Figure 1.) to provide the patient with a small prism-free area for binocular spot (short duration) reading.
4. If the patient does not wear distance-vision spectacles, Chadwick Optical will provide a pair of distance-vision spectacles (that may contain plano lenses).
5. **On data form A please record details of the spectacles (frame and lenses) on which the peripheral prisms are fitted.**

Notes:

1. The patient should also have a pair of glasses without peripheral prisms that can be used for extended reading once the lower prism segment is fitted. If the patient does not have such spectacles, Chadwick Optical will provide a pair of reading glasses.
2. Patients should NOT drive a car when wearing the peripheral prism glasses. Any patient who does drive should have regular glasses without prisms that he/she can use for driving. If necessary, Chadwick Optical will provide a pair of glasses for the study so that the patient can use their regular glasses for driving.

First fitting visit – upper prism segment

For the initial trial and training period patients are fitted with a 40^Δ Press-On™ Fresnel prism segment (supplied by Chadwick Optical, Inc.) on the upper part of the lens only. The upper segment prism should help the patients avoid obstacles in the upper field, such as kitchen cabinet doors, and overhanging tree branches. These prisms are also effective in avoiding obstacles that extend from the lower to upper fields, such as utility poles, tree trunks, and bus and traffic signs.

Fitting the upper peripheral prism

1. Before fitting the upper prism, ask the patient to walk around and observe the normal head posture that is used when walking. (This will be relevant in the subsequent section on adjustment of prism height)
2. Ensure that the spectacles on which the prism is going to be fitted are properly adjusted and do not tend to slide down the patient's nose. **The spectacles should fit securely in order to achieve a good prism fitting.**

3. The upper prism is fitted with its lower edge 6mm above the center of the pupil on the **inside surface** on the patient's lens.
 - a. Ask the patient to stand up in a normal and comfortable posture, holding the head straight and looking straight ahead at a target at eye level.
 - b. Mark the position of the center of the pupil on the lens with a marker (do not use a permanent marker!).
 - c. Mark the position of the lower edge of the prism on the lens 6mm above the center of the pupil
4. Orient a piece of press-on-prism in the base out direction and trim the piece of prism (using sharp scissors) so that it fits on the lens. Do not trim the top of the prism segment to fit perfectly - leave about 4mm overhang to allow for adjustments that will be made during the fitting process.
5. Apply the prism to the lens. For initial testing use a dry application on a very clean surface (wet application can be used for the final fitting after adjustments have been made.)
 - a. Make sure that the prism segment is well-positioned and stable
 - b. Verify that image shift is in the correct direction (base out – image shifts in). Images should be shifted from the temporal side to the nasal side (from the side of the field defect towards the functional visual field).
 - c. Make sure that the prism is clean and has as few air bubbles as possible. When you are cleaning the prism illustrate to the patient the cleaning procedure as described in the handout.
6. Demonstrate the effect of the prism by doing a binocular confrontation field.
 - a. Test first along the horizontal midline and then the lower field. Make sure that the patient is aware of the fact that he/she can only detect your hand (fingers) at his vertical midline (in line with his nose).
 - b. Test the upper field. Patient should be detecting your hand at about 20 degrees before midline. Make sure patient realizes that his/her detection through the prism is further into the periphery, by having him/her look directly at the hand, which requires eye and then head movement. Show him/her how far it is from his/her body midline where he/she detected the hand in the lower field.
7. On data sheet B, record the pupil center position (distance in millimeters from pupil center to the lower edge of the lens) and the initial fitting position of the upper prism segment (the distance in millimeters from the lower edge of the prism to the lower edge of the lens) – see Figure 1.

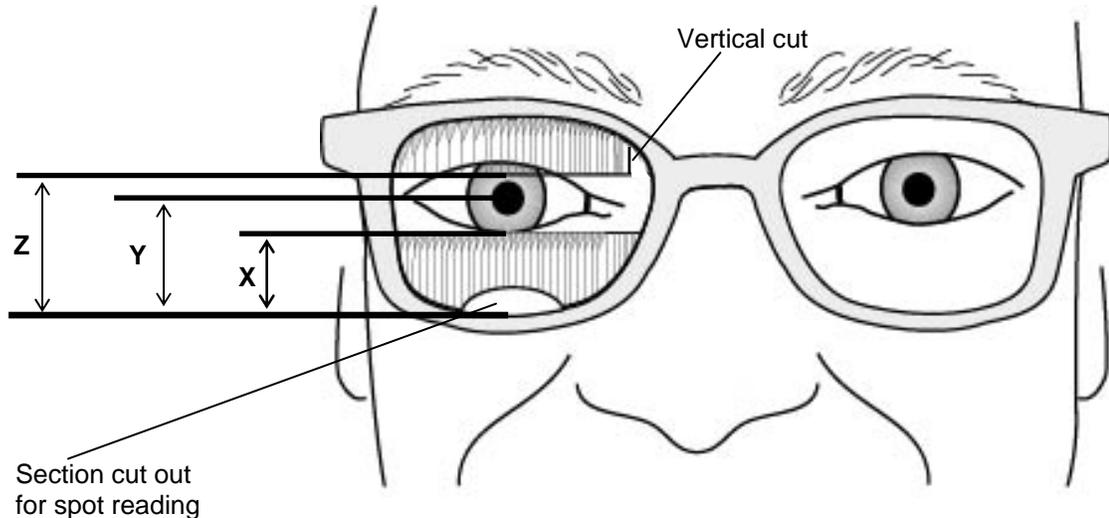


Figure 1. Diagram of both upper and lower peripheral prisms fitted to the right spectacle lens for a patient with right hemianopia. **X**, **Y** and **Z** are the measurements used to specify the fitting position of the lower prism segment, pupil center position and upper prism segment respectively relative to the lower edge of the spectacle lens. A small section has been cut out of the lower prism segment to provide a prism-free area for binocular spot reading. A vertical cut has been made on the upper prism segment closest to the nose pad to help patients to differentiate the upper and lower prism segments.

Training for use of the upper prism

1. The patient is instructed to look centrally only through the carrier lens, and not through the prisms. When an object of interest is detected through the prism (in peripheral vision) it should then be examined through the carrier lens by making a vertical (and, perhaps, horizontal) head movement. In normal vision, foveating eye movements usually precede such head movements. The patient's training consists of learning to avoid such eye movements or to follow them quickly with a head movement to eliminate the diplopia if it occurs (explain that diplopia refers to **central** diplopia that occurs if object of regard is viewed through the peripheral prism). In many ways the required behavior is similar to that needed with bifocals or progressive addition lenses, where head movements are needed to eliminate the blurry appearance of targets seen through the wrong part of the lens. Similarly, patients should realize that head movements require deliberate attention at first and should become almost automatic following training and practice (usually in less than a week).
2. Patients should be instructed to try to reach by hand and touch objects detected through the prism. First demonstrate to the patient that they miss the target when initially reaching for it in a ballistic fashion (i.e. with a fast movement and no correction during the movement). Present to the patient your open hand so that it can be seen on the non-hemianopic side and through the non-prism part of the lens. Ask the patient to touch your hand with his finger rapidly, while still looking towards your

eyes. The patient should be able to do this with no difficulty. Repeat until the patient's movements are rapid and accurate. Then present only one finger at the same general area. Have the patient strike at the finger. If the patient is able to do this, present the finger slightly into the hemianopic side so that it can be seen through the prism (patient should still keep looking towards your eyes). The patient is likely to miss the finger. Ask him to repeat the movements a few times until he is able to touch the finger seen through the prism with a rapid accurate movement. Explain that in time the first reach should become more accurate. Tell the patient to practice such touching movements to objects seen through the prism. Demonstrate the improvement on repeated reaching to the same object.

3. Have the patient walk on a simple indoor course such as corridors and into uncluttered rooms. Have the patient pay particular attention to door frames on the "blind" side. Have the patient walk up and down a set of stairs. The upper peripheral prism should not influence the ability to walk on stairs, but remind the subject to use handrails when available. **The patient should be escorted at all times.**
4. During the training walk, observe the head posture of the patient, and determine whether it is similar to the head posture adopted without the prism segment in position. (Ideally the patient should use a natural head posture when wearing the prism)
5. After the training walk, ask the patient what they thought about the position of the prism segment (whether it interfered with central vision).

Adjusting height of upper prism

The fitting height of the upper prism segment will be adjusted after the patient has completed the initial training walk (described above) and had an opportunity to become accustomed to the prism. The aim of the adjustment is to determine the lowest possible position at which the lower edge of the prism segment can be placed such that the prism does not interfere too much with central vision and a natural head posture can be used when walking.

1. a. If during the training walk head posture appears natural and the patient does not complain strongly of the prism interfering with vision, move the upper prism segment downwards by 2 mm from the initial fitting position (do not bother to trim the top of the prism segment to fit perfectly, this will be done at the end, after the final fitting position is determined) and then carry out steps i) – v) below.
- b. However if during the training walk the head posture is observed to be significantly **elevated** compared to the pre-fitting posture and the patient complains strongly about the prism interfering with vision, move the upper prism segment upwards by 1 mm from the initial fitting position and then carry out steps i) – v) below

- i) Repeat the walking exercise with the patient wearing the prism in the new fitting position. Observe the head posture and ask the patient whether the prism interferes with central vision.
 - ii) If the head posture is unchanged from the pre-fitting and there is no report of the prism interfering with central vision, move the prism 1mm further downwards and re-evaluate.
 - iii) If the head posture is elevated from the pre-fitting observation or the patient reports that the prism interferes with central vision, move the prism upwards by 1mm and then re-evaluate.
 - iv) Continue adjusting the vertical fitting position of the prism in this fashion to determine the **lowest** possible position at which the lower edge of the prism segment can be placed.
 - v) Record on data sheet B all fitting positions in the order they were evaluated, along with the head posture observations and patient responses for each position.
2. When the final fitting position is determined, trim the prism segment to ensure that it fits completely on the lens.
 - a. At the edge of the upper prism segment closest to the nose pad, make a small vertical cut and remove a small piece of prism (see Figure 1.). This will help patients to differentiate the upper prism from the lower prism if the prisms are removed or fall off the lens.
 - b. Make sure no part of the prism is hanging over the edge of the lens (bevel) or over the frame. The final application can be made dry on a very clean surface or wet with water or preferably using clear hair gel (available in every drug store). Make sure that the prism segment is well positioned and does not move (this may take some time if a wet application is used)
 3. On data sheet B record the final fitting position of the upper prism segment (the distance in millimeters from the lower edge of the lens to the lower edge of the prism).

Training and advice at end of visit

1. Provide the patient with a copy of the cleaning instructions, and review these instructions with the patient following the fitting and training of the upper prism segment.
2. Provide and review with patient the wearing instructions for upper prism segment.
3. Remind patient that if he/she encounters any difficulties to contact the office at which the prisms were fitted as soon as possible to discuss the difficulties and possible solutions. If the patient has extreme difficulties adapting to the prism, he/she should remove the prism from his/her glasses or wear other glasses without prisms and contact the office at which the prisms were fitted. (Any adverse events such as serious problems, injuries or accidents, should be reported to Dr Peli.)

Second fitting visit - lower prism segment, 2 weeks after first fitting

Experience with upper prism

At the start of the second fitting visit, interview the patient about the effect of the upper prism segment and his/her experience with it. Read the questions from data sheet C page 1 and record the answers.

1. If the patient's experience has been favorable (noting no ill effects or difficulties with the prism, regardless of whether or not the positive effect of the prism on avoiding obstacles was noted), the patient will be fitted with the lower prism segment (proceed to the section "fitting the lower peripheral prism")
2. If the patient's experience was unfavorable and problems were reported, **do not fit the lower prism**, first try to resolve the problem and then have the subject try the upper prism for another week.
 - a. Ask the patient whether he/she is willing to continue to use the peripheral prisms after possible adjustments have been made. The patient should be encouraged to continue, as it is quite possible that results with the peripheral prisms will improve with experience and practice (as is found with other visual aids, such as bifocals). However, the patient should not feel obligated to continue for the benefit of the study, only if they still feel that they might benefit from further experience.
 - i) Check that the peripheral prism has been correctly placed on the spectacle lens (make sure base is towards the direction of field loss).
 - ii) Check that the spectacles are worn in the way that they were when the height was determined (e.g. does the patient allow them to slide down the nose a lot?).
 - iii) Check that the patient is using the peripheral prisms correctly (e.g. should not notice diplopia, i.e. should not be fixating through the prism(s)).
 - iv) Investigate the possibility that a different peripheral prism height might be preferred – try moving upper prism 1 or 2mm higher.
 - v) Complete data form C page 1 (mark revision number "original") indicating the prism fitting positions evaluated, along with the head posture observations and patient responses for each position.
 - b. When the patient returns in 1 week after wearing the upper prism in the new position, re-interview the patient about his/her experience with the upper prism. Use a new data sheet C page 1 and record the answers to the questions. Mark this new data sheet C page 1 as revision number "2". If no problems are reported, proceed to fitting the lower prism; otherwise repeat the steps in part (a).

Fitting the lower peripheral prism

1. The lower prism is fitted with its upper edge 6mm below the center of the pupil.
 - a. Ask the patient to stand up in a normal and comfortable posture, holding the head straight and looking straight ahead at a target at eye level.
 - b. Mark the position of the center of the pupil on the lens with a marker (do not use a permanent marker).
 - c. Mark the position of the upper edge of the prism on the lens 6mm below the center of the pupil.
2. The 40^Δ Press-On™ Fresnel prism is trimmed so that the peripheral prism segment fits on the lens. Do not trim the bottom of the prism so that it fits perfectly on the lens - leave about 4mm overhang to allow for adjustments that will be made during the fitting process.
3. Apply the prism to the inside surface of the lens. Make sure that the prism segment is well-positioned, stable (does not move) and in the correct direction (base out).
4. Demonstrate the effect of the prism by doing a binocular confrontation field.
 - a. Test first along the horizontal midline. Make sure that the patient is aware of the fact that he/she can only detect your hand (fingers) at his/her vertical midline (in line with his nose).
 - b. Test the lower field. Patient should be detecting your hand at about 20 degrees before midline. Make sure patient realizes that his/her detection through the prism is further into the periphery, by having him/her look directly at the hand, which requires eye and then head movement.
5. On data sheet C record this initial fitting position of the lower prism segment (the distance in millimeters from lower edge of the prism to the lower edge of the lens) and the pupil center position (distance from center of pupil to the lower edge of the lens) – see Figure 1.

Training for use of the lower prism

1. The patient is then instructed in the use of the lower prism segment. When an object is noted through the prism, a vertical head motion (either up or down) is required to examine the object through the carrier lens and avoid diplopia. Lateral eye movement into the side of the field loss is required as well, but patients need no instruction to initiate this eye movement once an object is detected.
2. The patient should be taken for a trial walk in the corridor with the lower prism and then be asked to walk a path through a room with many chairs and small tables (e.g. reception rooms) as this is particularly useful in training the patients in the use of the prism and noting its effectiveness. **The patient should be escorted at all times.**
3. The patient should be further instructed in the use of the prism while going down stairs, which requires head lowering to see the stairs through the carrier lens. The use of handrails, whenever available, to improve stability and safety should be

emphasized. The lower peripheral prism is expected to have a greater impact on walking, both for initial interference (i.e. diplopia because the patient forgot to lower their head) and for more potential obstacle alerts.

4. During the training walk, observe the head posture of the patient and at the end ask the patient what they thought about the position of the prism segment (whether it interfered with central vision).

Adjusting height of lower prism

The fitting height of the lower prism segment will be adjusted after the patient has completed the training walk and had an opportunity to become accustomed to the lower prism. The aim of the adjustment is to determine the **highest** possible position at which the upper edge of the lower prism segment can be placed such that the prism does not interfere too much with central vision and a natural head posture can be used when walking

1. a. If during the training walk the patient had no difficulty with the lower prism position, move the lower prism segment upwards by 2 mm from the initial fitting position (do not bother to trim the top of the prism segment to fit perfectly, this will be done at the end, after the final fitting position is determined) and then carry out steps i) – v) below.
 - b. If during the training walk the patient reported difficulty with the lower prism position (or head position is lowered relative to the natural posture), move the lower prism segment downwards by 1 mm from the initial fitting position and then carry out steps i) – v) below.
 - i) Repeat the walking exercise with the patient wearing the prism in the new fitting position. Observe the head posture and ask the patient whether the prism interferes with central vision.
 - ii) If the patient has no difficulties, raise the lower prism segment upwards by another 1mm and re-evaluate.
 - iii) If the patient has difficulties (or head position is lowered relative to the natural posture), bring the lower prism segment position down by 1mm, and re-evaluate.
 - iv) Continue adjusting the vertical fitting position of the prism in this fashion to determine the **highest** possible position at which the upper edge of the prism segment can be placed.
 - v) Record on data sheet C, page 2 all fitting positions in the order they were evaluated, along with the head posture observations and patient responses for each position.
2. When the final fitting position of the lower prism segment is determined, trim the prism segment to ensure that it fits completely on the lens.
 - a. If the lower prism has been applied onto a bifocal or multifocal lens, cut a small section out of the bottom of the lower prism segment to provide the patient with a small prism-free area for binocular spot (short duration) reading. The cut-out

- should have a maximum height of about 3-4mm, and should only extend across part of the width of the lens (see Figure 1.)
- b. Apply the prism to the lens and make sure no part of the prism is hanging over the edge of the lens (bevel) or over the frame.
 - c. Make sure the prism is well positioned and does not move on the lens.
3. Record the final fitting position of the lower prism segment onto data sheet C, page 2.

Training and advice at end of visit

1. Instruct again in the care and cleaning of the prisms and in reinstalling the prism segment in case it peels off the lens while being cleaned. Give another copy of the care and maintenance instructions to the patient.
2. Provide and review with patient the wearing instructions for glasses containing both upper and lower prism segments.
3. Remind patient that if he/she encounters any difficulties to contact the office at which the prisms were fitted as soon as possible to discuss the difficulties and possible solutions. If the patient has extreme difficulties adapting to the prisms, he/she should remove the prisms from his/her glasses or wear other glasses without prisms and contact the office at which the prisms were fitted. (Any adverse events such as serious problems, injuries or accidents, should be reported to Dr Peli.)

Telephone follow up - 2 weeks after second fitting

Interview the patient by telephone to determine their experience with wearing both prism segments (read the questions on data sheet D and record patient responses). Provide further advice on wearing, cleaning, etc., as necessary. Remind the patient to wear the prisms as much as possible for indoor and outdoor activities (except prolonged reading). Suggest to the patient that they start to use the prisms in more complex situations such as in unfamiliar places.

Follow up visit – 4 weeks after second fitting

1. At the follow up visit, interview the patient about the effect of the prisms and their experience with them. Read the questions from data sheet E page 1 and record the answers.
2. If the patient's experience has been favorable (noting no ill effects or difficulties with the prism whether or not the positive effect of the prism on avoiding obstacles was noted), reach a clinical decision as to whether the patient should continue wearing the prisms.

3. If the patient's experience was unfavorable and problems were reported, attempt to resolve the problem before reaching a clinical decision to discontinue prism wear. If the patient is willing, have the patient try the upper and lower prisms for another week.
 - a. The patient should be encouraged to continue; however, the patient should not feel obligated to continue for the benefit of the study, only if they still feel that they might benefit from further experience.
 - i) Check that the peripheral prism has been correctly placed on the spectacle lens (make sure base is towards the direction of field loss).
 - ii) Check that the spectacles are worn in the way that they were when the height was determined (e.g. does the patient allow them to slide down the nose a lot?).
 - iii) Check that the patient is using the peripheral prisms correctly (e.g. should not notice diplopia, i.e. should not be fixating through the prism(s)).
 - iv) Investigate the possibility that a different peripheral prism height might be preferred – try moving lower prism 1 or 2mm lower.
 - v) Complete data form E page 1 (mark revision number “original”) indicating the prism fitting positions evaluated, along with the head posture observations and patient responses for each position.
 - b. When the patient returns in 1 week after wearing the lower prism in the new position, re-interview the patient about his/her experience with the upper prism. Use a new data sheet E page 1 and record the answers to the questions. Mark this new data sheet E page 1 as revision number “2”. If no problems are reported, reach a clinical decision as to whether the patient should continue wearing the prisms; otherwise repeat the steps in part (a).
4. Record the final clinical decision and the final fitting positions of the upper and lower prisms on data sheet E pg. 2.
5. Make arrangements for continuing clinical care of the patient by you, as necessary. Explain to the patient that this is the end of the study and further dealing with the situation will be on based on clinical needs and patient wishes.

References

Peli, E. (2000). Field expansion for homonymous hemianopia by optically induced peripheral exotropia. *Optometry and Vision Science*, 77, 453-464.

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