COVER PAGE

STUDY TITLE: ASSESSMENT OF THREE BASIC PROGRESSIVE LENS DESIGNS

REGISTRATION NUMBER: NCT05252871

DATE: 09/27/2021

STUDY PROTOCOL

STUDY DESIGN:

This study was a non-invasive double-masked randomized clinical investigation. The interventional model was parallel assignment, and the study was triple-masked (participant, investigator, and outcomes assessor). For this study, 83 participants were recruited over a period of 3 months, 80 patients were enrolled into the study, and 3 participants were excluded since they did not meet the inclusion criteria.

STUDY OBJECTIVES:

The primary purpose of the study was to evaluate the preference, adaptability, and visual performance of three basic progressive lens designs.

PRIMARY ENDPOINT:

Evaluation of the preference among progressive lens designs.

STUDY SUBJECTS AND RECRUITMENT:

Study subjects were experienced progressive addition lens wearers, which were recruited by advertisements, by email, and with direct person-to-person solicitation.

Inclusion criteria: 1. Subjects should were experienced progressive lens designs wearers who have worn their current prescription for at least one month; 2. The designated progressive lens designs wearers had no issues about wearing a progressive lens design; 3. Age: 45 to 70 years old; 4. Visual Acuity (decimal): far & near monocular cc ≥ 1.0; 5. Normal binocular vision (at distance & near: no strabismus on cover testing, aligning prism of less than 2Δ horizontally or vertically, stereoacuity of 2' or better at distance and near); 6. New prescription (found at visit#1) was in the range: (a) Spherical power: less than +/-6.00 D; (b) Cylindrical power: less than -2.75 D minus cylinder; (d) Addition: 1.50 D - 2.50 D; (e) Difference in the power (spherical equivalent) between eyes: less than 2.00 D; (f) 7. Understanding and speaking English or Spanish to be able to answer questionnaires.

Exclusion criteria: 1. Subjects who have never worn any progressive lens designs or have not worn their current progressive lens design for at least one month. 2. Age: younger than 45 years or older than 70 years. 3. Visual Acuity (decimal): far & near monocular cc < 1.0. 4. Binocular vision problems (at distance & near: strabismus on cover testing, aligning prism of 2Δ or greater horizontally or vertically, stereoacuity of less than 2' at distance and near). 5. New prescription (found at visit#1) is: (a) Spherical power: more than +/-5.75 D; (b) Cylindrical power: more than -2.50 D minus cylinder; (d) Addition: less than 1.50 D or more than 2.50 D; (e) Difference in the power (spherical equivalent) between eyes: more than 1.75 D; (f) Different from current prescription more than 0.50 D in any meridian 7. Known ocular disease that affect visual acuity. 8. Vertigo or a balance problem.

Potential study subjects were contacted by the study coordinator. At this time, the study coordinator assigned a subject ID and scheduled each subject for their first visit.

PROGRESSIVE ADDITION LENSES:

Each lens pair for each study subject was specifically made to the subject's up-to-date prescription. To assure optimal vision, all lenses possessed anti-reflective coatings and were clear (not tinted). Each frame was fitted to the patient's anatomic features to assure an optimal wearing experience. In addition, all subjects were reminded of the specifics of progressive addition lenses, their appropriate use, and that a short period of visual adaptation might be required.

DATA MONITORING:

Throughout the entire duration of the study, data monitoring was conducted by the Center for Clinical Research at Western University of Health Sciences. This involved checking of consent forms being signed dated, checking for the completion of source documentation and clinical research forms and clinical binders.

STUDY PROCEDURES:

All three visits were conducted in the Eye Care Institute, WesternU Health Pomona, 795 E. Second Street, Pomona CA 91766.

During Visit #1:

- The visit started with an explanation of the study and a discussion of the informed consent form for which signatures were obtained. Then a set of screening questions was asked.
- Subjects, who meet the inclusion criteria continued in the study, received an eye examination, and a new progressive addition lens prescription.
- Each eligible study subject reported visual experiences with their currently worn progressive addition lenses.
- Each subject then selected one appropriate spectacle frame from a selection of high-quality frames made from titanium material. For this selected frame, the patient's fitting data were obtained.

Between Visit #1 and Visit #2:

- The PI communicated the subject-ID along with the prescription data and the selected spectacle frame model to the spectacle manufacturer. Based on this information, the manufacturer made three pairs of glasses with the different lens designs for each subject. All three pairs were manufactured with the frame model that the patient selected at visit #1. A maximum of one month was planned for production and delivery of the progressive addition lenses.
- The primary investigator, co-investigators and the subject were blinded to which basic progressive lens designs were used by the manufacturer. To reduce evaluation bias stemming from the wearing sequence for the lens design, the PI adopted a stratified permuted block randomization, based on the average lens power data which were computed from the prescriptions found during visit #1. This wearing sequence was assigned for each study subject. During the manufacturing process, the frames had small marks on their temples to distinguish each for the assigned wearing sequence.

During Visit #2:

- Each study subject received three pairs of progressive addition lenses, that were adjusted and fitted. At this time, an assessment of distance and near visual acuity was

conducted. Then the subject evaluated first visual impressions with all pairs, one after another, after 10-15 minutes of wearing time.

- Afterwards, the first pair was handed to the subject and the second and third pairs were placed in sealed envelopes along with one set of evaluation surveys
- Each subject was instructed:
  - to only wear the first assigned (and labelled) pair of progression addition lenses for one week (this is the first week of the trial), while carefully observing the ease of visual adaptation and visual experiences.
  - to only wear the second assigned (and labelled) pair of progression addition lenses in week two of the trial. This pair is also worn for one week, while carefully observing the ease of visual adaptation and visual experiences.
  - to only wear the third assigned (and labelled) pair of progression addition lenses in week three of the trial. This pair is also worn for one week, while carefully observing the ease of visual adaptation and visual experiences.

Between Visit #2 and Visit #3:

- Study subjects wore the three pairs of progressive addition lenses in the sequence explained during visit #2.

During Visit #3:

- During visit #3, each study subject returned with the three pairs of progressive addition lenses. First, an assessment of distance and near visual acuity was conducted. Then, each participant returned all progressive addition lens pairs to the investigator along with the satisfaction questionnaires regarding the adaptability and visual performance for each progressive addition lens pair. Finally, each patient completed a final comparison questionnaire of all 3 progressive addition lens pairs and ranked them as “the best”, “good”, “the worst”. At this point, the study ended for each subject, all 3 pairs of glasses were returned, and subjects were reimbursed for their time and effort.

DATA ANALYSIS:

Data analysis includes Analysis of Variance (ANOVA) or its non-parametric alternatives with post-hoc tests and correlation analysis.