THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

INFORMATION SHEET

Quality of Life in Presbyopes Using Single-vision Lens and Progressive Lens Correction: A Randomized Controlled Trial

You are invited to participate in the above project conducted by Prof Mingguang He, who is a staff member of the Department of Optometry in The Hong Kong Polytechnic University. The project has been approved by the PolyU Institutional Review Board (PolyU IRB) (or its Delegate) (Reference Number: HSEARS20240916011).

Before committing to this study, please review this document to understand its purposes, study procedure, and the possible benefits and risks involved. We encourage you to discuss this with your close ones and address any queries to our research team.

Background and Purpose of this Study

1.1 Background

Presbyopia is a common age-related condition characterized by the progressive decline in the eye's ability to focus on nearby objects, due to loss of lens accommodation. The elderly population experiencing presbyopia has been growing significantly, affecting between 1.09 billion and 1.80 billion people globally.Presbyopia has a profound impact on quality of life, particularly during close-up tasks such as reading, working, or using digital devices. To address this widespread issue, various interventions have been developed, including near-vision spectacles, contact lenses and surgical treatments. Among these, near-vision spectacles remain to be the predominant method for presbyopia correction.

Spectacle correction of presbyopia includes bifocal or trifocal lenses, and progressive lenses. Single-vision spectacles (SVS) for near work are the simplest form of presbyopia correction. They are the most affordable and have a short adaptation period. However, individuals who rely on single-vision lenses need to switch glasses when shifting focus between distant and near tasks, which can be cumbersome and disruptive. Progressive addition lenses (PALs) are designed with a gradual transition in refractive power across their surface, offering enhanced converging powers for eyes and enabling sharp vision at various distances. PALs allows users to see clearly through gaze relocation, potentially enhancing the quality of life for individuals with presbyopia. However, PALs come with their own set of challenges, such as adaptation issues and peripheral distortion. Therefore, it is crucial to to investigate the impact of these two types of glasses on the quality of life (QOL) in order to better guide the presbyopic people in wearing glasses.

1.2 Purpose

This study aims to compare the QOL of presbyopes wearing PALs with that of those wearing SVS for near correction.

2. Inclusion and Exclusion Criteria

2.1 Inclusion criteria

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We are looking for individuals who meet the following criteria:

- Age 40 – 70 years;
- A distant correction of ≤2D for hyperopia, or ≥-5 D for myopia, or < 2D for astigmatism in both eyes;
- Anisometropia of less than 1.50 D;
- Distance visual acuity of at least 0.3 decimal, and near VA ≦ N8 (20/50) at 40 cm with habitually worn distance refractive correction, with improvement of near vision by at least one line with the use of a plus lens;
- Have not undergone any near correction in the past six months;
- Able to answer a questionnaire;
- Giving written consent to participate in the study.

2.2 Exclusion criteria

- Ocular abnormalities leading to visual impairment including severe cataract, glaucoma, strabismus, and ocular fundus diseases based on self-report or slit-lamp examination;
- Severe physiological and psychological diseases affecting follow-up;
- History of cataract surgery, phakic intraocular lens surgery, corneal inlay surgery, radial keratotomy, or any intraocular surgery affecting the refractive status of the eye;
- Have used pilocarpine in the past six months.

3. Study procedures

3.1 Study design

This prospective, dual-arm, randomized clinical trial will enroll prebyopes aged 40-70 years who wear PALs or SVS. The study aims to compare the QOL of presbyopes wearing PALs with that of those wearing SVS for near correction.

All optical stores involved in the study will provide the PALs or SVS for participants. Eligible participants will be randomly assigned in a 1:1 ratio to either the PALs group or the SVS group. Participants in the PALs intervention group will receive 1-month progressive lens correction in daily life. And participants in SVS intervention group will use near-vision spectacles during near work and use their original habitual distant glasses for distance tasks for 1 month.

The study will compare the QOL scores measured by a 12-item Near Vision-Related Quality of Life questionnaire between the two groups. Additionally, the study will compare the scores measured by the Refractive Status and Vision Profile questionnaire and Visual Analogue Scale between the two groups as well as assess the change in the above three questionnaires scores at 1 month following enrollment. And best-corrected visual acuity of subjects will also be assessed at baseline and at the 1-month follow-up.

3.2 Standard care procedures

First of all, pre-screening activities will be conducted, including gathering information about paricipants' ages, refractive status and histories of ocular diseases. Prior to participation in the study, informed consent will be obtained from the presbyopic subjects. The detail eligibility criteria will then be assessed. Information from the participants, including demographic and visiting details, life and work habits, medical history, pre-treatment data, ocular measurements, questionnaire scores of vision-related quality of life, will be collected by on-site doctors or

optometrists during baseline and follow-up examinations. Subjects will wear glasses during their routine activities. Additionally, records of treatment adherence, self-reported side effects, and any discontinuation of treatment will be gathered.

3.3 Time required

- The total study duration is 1 month.The PALs intervention group is expected to use PALs in daily life. And the SVS intervention group is expected to use near-vision spectacles during near work and use their original habitual distant glasses for distance tasks.
- Attending Scheduled Visit: Participants are expected to visit the clinic at 1 month after the initiation. The exact timing of the visit may vary depending on the clinic's routine. Generally, each visit is estimated to take 1 to 2 hours.

4. Benefits and Risks

4.1 Benefits

Participants' potential asymptomatic or preclinical ocular diseases may be detected and treated early due to participation in research examinations.During the study period, the participant will be followed up by a dedicated personnel, providing convenience for consultations. The information gathered from this research may help other patients in the future.

4.2 Risks and Discomforts

Potential side effects, such as adaptation issues, eye strain, temporary glare or dizzy, may occur, particularly when participants persistently work at near distances for a long time. However, these effects are expected to be minimal and transient. Participants will be advised to take regular breaks to mitigate such risks. Any adverse events or discomfort experienced by the participants during the study will be closely monitored and reported. This includes unexpected reactions to the PALs or SVS, such as persistent eye strain, headaches, or changes in visual acuity.

Safety data will be continuously collected throughout the study. This data will include any reports of discomfort, side effects, or other health concerns related to the use of the PALs or SVS. The study will ensure that all participants are fully informed about the potential risks and safety measures associated with the use of presbyopic spectacles.

5. Confidentiality Issues

The information you provide as part of the project is the research data. Any research data from which you can be identified is known as personal data. Personal data does not include data where the identity has been removed (anonymous data). We will minimize our use of personal data in the study as much as possible. The researcher and his team, supervisor, collaborator will have access to personal data and research data for the purposes of the study. Responsible members of The Hong Kong Polytechnic University may be given access for monitoring and/or audit of the research.

All information related to you will remain confidential and be securely encrypted and stored with de-identification to ensure privacy. Confidentiality is mandated by agreements for all parties involved. The information collected will be kept until 5 years after project completion. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation,

unauthorized access or destruction of the information you provide.

6. Rights of the subject

Withdrawals

A study investigator will terminate participation in the study for the following reasons:

- Any severe adverse event (a sudden loss of vision > two lines, or a scotoma developed in the centre of the visual field).
- The participant meets an exclusion criterion (either newly developed or not previously identified) that precludes further study participation.
- Any other reason in the Investigator's opinion.
- Safety information becomes available to stop study.

You are free to withdraw from participation in the study at any time upon request. Who withdraw from the study will be surveyed for reasons for withdrawal. Permission to utilize the data collected before withdrawal will be requested. If you decline, all your data will be deleted from the record system. Additionally, you retain the right to request access to and correction of any personal data you have provided for the project.

Inquires

If you have any questions, you may ask our helpers now or later, even after the study has started.

You may contact Dr Chen Yanxian (tel. no.: +85227666111/ email: yan-xian.chen@polyu.edu.hk) of PolyU under the following situations:

a) if you have any other questions in relation to the study; or
b) if, under very rare conditions, you become injured as a result of their participation in the study; or
c) if you want to get access to/or change your personal data before (31/12/2025).

In the event that you have any complaints about the conduct of this research study, you may contact the Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) stating clearly the responsible person and department of this study as well as the Reference Number.

In case of a serious adverse event[1] affecting your child, please report to the Principal Investigator/Chief Investigator immediately and the Principal Investigator/Chief Investigator will be required to report it to the PolyU IRB within 48 hours upon the receipt of your report.

[1] SAE is any adverse event that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity
- Results in congenital anomalies or birth defects
- Is another condition which investigators judge to represent significant hazards

Thank you for considering participating in this study.

Prof Mingguang He
Principal Investigator/Chief Investigator

(Reference: NIA Adverse Event and Serious Adverse Event Guidelines. https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf)

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