PARTICIPANT INFORMATION SHEET

HELIOS Trial
« Assessment of a New Generation of Progressive Addition (Varifocal) Lenses: Hoyalux iD MyStyle V+ »

Dear Madam/Sir,

You have been invited to participate in a clinical study, sponsored by HOYA, because you are wearing progressive addition (varifocal) lenses. This clinical study compares the performance of two progressive addition lenses, Hoyalux iD MyStyle V+ and Hoyalux Summit Trueform.

Before you agree to participate in this study, it is important that you clearly understand the study objectives and any study constraints.

Please, read carefully the following information and take the time you need to speak about with your family if necessary.

In case you may need further information regarding this study, do not hesitate to contact the study optometrist to ask any questions.

This information sheet describes your rights and obligations as a study participant. If you agree to participate in this study, you will be given a signed copy you should keep.

Your participation in the study is entirely voluntary. If you agree to participate, please note that you can decide at any time to stop participating, for any reason, by informing the study optometrist. You are not required to justify your withdrawal, and your present or future medical and optometric care will not be affected.

- **Why is this study being performed?**

Nowadays, many different types of progressive addition (varifocal) lenses are available to correct distance and near vision in people over the age of 40 years. Progressive addition lenses provide a more natural correction for people over the age of 40 due to a gradual increase of lens power from the top of the lens (giving clear distance vision) to the bottom of the lens (giving clear near vision). However, some wearers still experience adaptation problems (such as objects appearing to "swim" or eyestrain) and this can be more problematic if there is a difference in the optical prescription of the two eyes.

Binocular Harmonization Technology (BHT) has been developed by HOYA to take into the account the prescription of each eye individually. BHT should make it easier for the two eyes to work together as a team and also facilitates more rapid adaptation.

The purpose of the Helios study is to evaluate the adaptability and visual performance with progressive addition that have an advanced individualised design with BHT compared to conventional progressive addition. The two types of lenses that we are comparing in this study are Hoyalux iD MyStyle V+ and Hoyalux Summit Trueform. Both lenses are currently in widespread use by many patients in several countries.

- **How and where will this clinical study be conducted?**

The Helios study will be conducted in 2 sites in Europe (one in France and the other one in the UK). Approximately 60 participants will participate in the study (30 in each site). The total study duration would be 9 months, but the estimated study duration for participants would be approximately 4 months (including the time to manufacture lenses).

If you agree to participate in the study, you will be asked to visit the study optometrist who will carry out some eye tests to confirm whether you are suitable to participate. Once the study optometrist confirms your participation, you will be asked to attend for four further visits (please see the table below for details).

At each visit, the study optometrist will carry out tests to assess how well you see. You will be asked to complete some questionnaires about your vision, comfort, and quality of life when wearing your lenses. It is important that you answer these questionnaires as honestly as possible.

Participation in this clinical study will not imply other restrictions on your normal lifestyle, but you will be asked to wear the research glasses for at least 7 hours a day. In the unlikely event that you experience problems that make it difficult for you to wear the glasses for 7 hours a day then you should not wear them but instead contact the research team as soon as possible.

- **What would taking part involve?**

Each participant will test alternatively the Hoyalux iD MyStyle V+ and the conventional progressive addition lenses for a period of two weeks each (with a follow-up visit in the third weeks).

During the first visit a computer will perform the equivalent of tossing a coin to determine which pair of glasses you will received first.

The lenses will be glazed by HOYA into two identical spectacle frames of your choice. Neither you nor the study optometrist will know which lenses will be used first and second.

At the end of the study, you will be asked to choose the progressive addition that suit you best and you will be allowed to keep both pairs of glasses, if you would like to.

Visit	Examinations/Procedures
1	Questions about eye health & previous history of eye problems Measuring of current glasses Eye tests Questionnaire about eyestrain Choice of spectacle frames, fitting, and measurements
2	Collection of first pair of research spectacles & measurement of vision with these
3	Questionnaire about performance of research spectacles 1 Vision tests with first pair of glasses Dispensing of second pair of research spectacles
4	Questionnaire about performance of research spectacles 2 Vision tests with second pair of research spectacles Re-issued with both pairs of glasses to try on alternate days
5	Final comparison questionnaire and choice of preferred glasses Speed of reading test with both pairs of glasses

- **What are the possible benefits of taking part?**

There is no guarantee that you will experience any benefit during your participation in this clinical study. You will be allowed to keep both pairs of glasses at the end of the research. The results of the research will help further understanding of wearer preferences with different designs of progressive addition lenses.

- **What are the possible disadvantages and risks of taking part?**

Some research indicates that older people at risk of falls should not wear progressive addition lenses when they are walking or climbing steps, especially if they are not used to wearing progressive addition lenses. Other identified risks are that occasionally wearers notice mild eyestrain, peripheral distortions, and a "swimming" effect during adaptation. These mild problems usually disappear in time. It should also be stressed that the progressive addition lenses used in this research have been commercially available for some years and the adaptation required of wearers in this study is no different to adaptation required of wearers when these lenses are routinely supplied by opticians and optometrists.

- **What alternatives are available to potential participants?**

You could obtain a prescription for progressive addition lenses without participating in the study.

- **Are there any additional expenses for potential participants?**

Your participation is free of charge. The progressive addition lenses and spectacle frames will be provided by HOYA. Reasonable travelling expenses (e.g., second class rail fare) for reaching the research site they will be reimbursed on request.

- **How will my information be kept confidential?**

Your participation in the study will be recorded in a study clinical record. Your personal data collected for this trial will be anonymised using a unique participant identifier number. The collection and processing of your personal data will be limited to the data that are necessary to evaluate the spectacles used in this study. That means your name, address or telephone numbers will not be used as part of the study.

All data will be collected and processed with adequate precautions to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. Scientific publications, if any, will not mention the names of any participants and will not include photographs of participants.

- **Who will have access to my data?**

The Sponsor (Hoya) and research study team may have access to your study clinical record to monitor or analyse your data. Your anonymised data can also be communicated to European Health Authorities or health professionals who are bound to professional confidentiality. In any case, persons whose responsibilities require access to your personal data agree to keep your identity confidential.

You have the right to request through the study researchers access to your personal data and the right to request rectification of any data that are not correct or complete. Reasonable steps will be taken to respond to such a request, taking into consideration the nature of the request, the conditions of the study, and the applicable laws and regulations.

- **What if something goes wrong?**

Should your participation in this trial cause any damage to your health, the following insurance cover has been contracted by HOYA: Insurance policy number to be added.

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