

# Visual performance and satisfaction with multifocal contact lenses

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<b>Registration date</b> 05/08/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/09/2019	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Presbyopia is a condition associated with aging in which the eye's ability to focus on near objects gradually becomes more difficult. Multifocal contact lenses can be used to help individuals with presbyopia to see objects both in the distance and up close; however, how well these contact lenses perform depends on the wearer's prescription, the activities that they are conducting and the lighting conditions. The purpose of this study is to measure vision with a series of multifocal contact lenses under various conditions of use.

### Who can participate?

Adults who are at least 40 years old and who have healthy eyes other than for needing a near vision correction.

### What does the study involve?

Each participant have their eyes examined by the investigator and then are fitted with two to three types of multifocal contact lenses. A series of measurements of their vision are taken with each of the pairs of multifocal contact lenses. They are then asked to read letters of different sizes on both a computer screen and on smaller electronic tablets under bright, normal and dim lighting conditions. Each participant then completes a series of tasks while wearing the contact lenses. These include walking outdoor, carrying out a "word search" task and entering some data on a computer and reading and entering some details on a smart phone. The purpose of all of these tasks is not to see how well each participant completes them but for them to let the investigators know how satisfied they are with their vision while completing the tasks. All study participants will undergo the same series of vision tests and tasks.

### What are the possible benefits and risks of participating?

The possibility exists that participants may not directly benefit from participation in this study. They may, however, contribute scientific research information that may be used in the development of new, perhaps more successful, contact lenses. The examination and assessments are free and can be considered beneficial. All contact lenses have the potential of causing serious injury to the eye. Due to the nature and duration of the study the risks of participating in this study are considered to be similar to those of normal contact lens wear. It is possible that the following problems may occur with the use of contact lenses: eyes stinging,

burning, itching (irritation) or other eye pain; comfort is less than when lens was first placed on the eye; feeling that something is in the eye such as a foreign body or scratched area; excessive watering (tearing) of the eye; unusual eye secretions; redness of the eye; reduced sharpness of vision (poor visual acuity); blurred vision, rainbows, or halos around objects; sensitivity to light (photophobia); or dry eyes. If a participant experiences any of these, they should let the investigator know as soon as possible. In rare instances, corneal ulcers, scarring, the growth of blood vessels into the cornea, temporary or permanent decreased vision, iritis and infections of the eye requiring treatment might occur.

Where is the study run from?

The study is being conducted by Ocular Technology Group – International and is being run at their research clinic at 66 Buckingham Gate, London SW1E 6AU (UK)

When is study starting and how long is it expected to run for?

July 2016 to December 2016

Who is the main contact?

Ms. Trisha Patel

tpatel@otg.co.uk

## Contact information

**Type(s)**

Public

**Contact name**

Ms Trisha Patel

**Contact details**

66 Buckingham Gate

London

United Kingdom

SW1E 6AU

## Additional identifiers

**Protocol serial number**

CV 16-51

## Study information

**Scientific Title**

Visual performance and visual satisfaction measurement with multifocal contact lens combinations

**Study objectives**

No information is currently available regarding the relative visual performance and acceptance of the multifocal contact lens combinations to be tested. Therefore, the study will be an

exploratory investigation to further the understanding of the effect of the optical design and fitting approach of multifocal contact lenses on visual performance and acceptance with a view to selecting the optimal lens designs for early, intermediate and advanced presbyopes.

No formal hypothesis is to be tested, however, the underlying assumptions for the study are that:

- i. For specific visual environmental / activity situations the test combination achieving the best visual performance will also achieve the best visual acceptance;
- ii. For specific visual environmental / activity situations the test combination achieving the best binocular summation (a marker of binocularity) will also achieve the best visual acceptance.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

National Research Ethics Committee - South Central - Berkshire B, 14/07/2016

### **Study design**

Two phase, single arm, non-interventional, prospective, crossover study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Presbyopia

### **Interventions**

Visual performance will be measured binocularly (both eyes together) and monocularly (one eye at a time) using letter charts that are presented on either a monitor and on tablets (as applicable) at six distances under three lighting conditions (equivalent to outdoor daytime, indoor and outdoor nighttime). In addition participants will be asked to rate their satisfaction with their vision while wearing each of the contact lens types being evaluated.

The study will be conducted using a cross-over design. That is, each of the contact lenses to be evaluated will be worn as a pair, but the order that each of the pairs are worn in will be determined at random. All contact lens pairs will be worn by all participants in each of the study phases.

### **Intervention Type**

Device

### **Phase**

Not Specified

### **Primary outcome(s)**

This is a non-dispensing cross-over study and the primary endpoints will be measured at each of the visits when the test contact lenses are worn. There are a total of 2 to 3 test visits.

1. Measurement of binocular visual acuity at six distances (400, 200, 100, 67, 50, 40cm) at three

luminance levels (250cd/m<sup>2</sup>, 50cd/m<sup>2</sup> and 2.5cd/m<sup>2</sup>). Measurements will be made using letter charts with each of the types of contact lenses being evaluated

2. Visual satisfaction ratings on visual analogue scales and Likert scales with each of the types of contact lenses being evaluated

### **Key secondary outcome(s)**

This is a non-dispensing cross-over study and the primary endpoints will be measured at each of the visits when the test contact lenses are worn. There are a total of 2 to 3 test visits.

1. Measurement of monocular (right and left eyes) visual acuity at six distances (400, 200, 100, 67, 50, 40cm) at three luminance levels (250cd/m<sup>2</sup>, 50cd/m<sup>2</sup> and 2.5cd/m<sup>2</sup>). Measurements will be made using letter charts with each of the types of contact lenses being evaluated.

### **Completion date**

31/12/2016

## **Eligibility**

### **Key inclusion criteria**

There are no requirements as to participant race, gender or occupation.

In order to be enrolled, each participant shall meet the following criteria:

1. At least 40 years old
2. Have read and understood the Participant Information Sheet
3. Have read, signed and dated the Informed Consent
4. Current spectacle or soft contact lens wearer
5. Spectacle refraction:  
Distance: Sphere: -6.00D to +4.00D; Astigmatism: 0.00D to -0.75D  
Near Addition: Group 1 (Phase 1) - +1.00 to +1.50D; Group 2 (Phase 2) – Subgroup A +1.75 to +2.00D; Subgroup B +2.25 to +2.50D
6. Best corrected visual acuity in each eye of at least 20/25
7. Have normal eyes with the exception of the need for visual correction
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

To be eligible as a participant, each candidate shall be free of any ocular or medical condition that may affect the results of this study.

The following are specific criteria that exclude a candidate from enrolment in this study:

1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would

contraindicate contact lens wear

2. Use of systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens;
4. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit;
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. Enrolment of the investigator or his/her staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals
8. Participation in any clinical trial within 30 days of the enrolment visit

**Date of first enrolment**

25/07/2016

**Date of final enrolment**

01/12/2016

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Ocular Technology Group - International**

66 Buckingham Gate

London

United Kingdom

SW1E 6AU

## **Sponsor information**

**Organisation**

CooperVision Inc.

## **Funder(s)**

**Funder type**

Industry

**Funder Name**  
CooperVision Inc.

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not expected to be made available