

# Comparison between a novel device and conventional sight testing methods to determine spectacle prescription: Accuracy and speed of measurement

<b>Submission date</b> 23/05/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/11/2022	<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

As the population ages, the pressure on hospital eye services is increasing. As a result, optometry-based enhanced eye care services are being developed to manage certain patient groups within the community. As their role widens, optometrists (eye doctors) spend more time on the investigation and management of eye diseases using a range of medical devices, with the measurement of the patient's glasses prescription forming an ever smaller proportion of the eye examination. This means that patients often have to change seats many times so that the different devices can be used, which requires space in the optometric clinics and a longer time for standard eye examinations. This study is going to investigate whether a novel device to measure a patient's glasses prescription, can help to save time and space in optometric clinics, while still accurately determining the glasses prescriptions. The device combines two currently used devices that measure and refine the glasses prescription, reducing the number of times the patient has to change seats during an eye examination. The aim of this study is to find out whether the novel device is an effective way of saving time and space in an optometric clinic whilst providing accurate results.

### Who can participate?

Registered, returning customers aged between 13 and 45 attending the participating optometry practice for a routine eye examination that have good vision in both eyes.

### What does the study involve?

All participants undergo their normal eye examination as planned. This involves measuring the time taken to assess their glasses prescription, including the time taken to move between seats placed at the different measuring devices used in the examination. Following this, participants have their prescription measured again using the novel device. The prescriptions measured using the novel device and the conventional techniques are compared, along with the time taken to determine the spectacle prescription in each case.

What are the possible benefits and risks of participating?

There are no specific benefits to participants taking part in the study. Participants will not receive payment and will have to pay for their eye examination as normal if they are a private patient. There are no known risks to being involved in the study, other than a small risk of feeling tired during the testing, but participants will be offered the opportunity for a break to minimise this risk. If a patient needs glasses, the results from the novel device being tested will not be used to determine the strength of any glasses prescribed.

Where is the study run from?

A community optometry practice located in Sale, Cheshire (UK)

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

May 2016 to September 2016

Who is funding the study?

Topcon Eye Care Company (Japan)

Who is the main contact?

Dr Catharine Chisholm

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Catharine Chisholm

**Contact details**

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## Additional identifiers

**Protocol serial number**

T\_SS\_BEC\_2016ct001

## Study information

**Scientific Title**

Comparison of the accuracy and duration of refractive error measurements determined using a novel, semi-automated measuring device versus conventional refraction techniques, in a normal optometric population

**Study objectives**

The prototype device improves workflow in terms of time, space saving and patient journey, while maintaining accuracy in the measurement of refractive error, compared to the conventional methods of measuring refractive error.

### **Ethics approval required**

Old ethics approval format

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

Not provided at time of registration

### **Study design**

Single-centre non-randomised pilot study

### **Primary study design**

Interventional

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

Other

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

Refractive error

### **Interventions**

Participants will have their refractive error measured as part of their standard eye examination (auto-refractor and subjective refinement using a phoropter and letter chart), during which the time taken to determine their prescription will be measured.

Participants will then have their refractive error measured using the prototype device. The measurement and the time taken to determine the measurement, will be compared with the refractive result determined during the standard eye examination using conventional methods.

### **Intervention Type**

Device

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

1. Time taken to measure refractive error, including movement of participant between devices during the eye examination is measured using a stopwatch
2. Refractive outcome (sphere and cylinder) measured during the eye examination using conventional methods and with the prototype device (undertaken after the eye examination)
3. Number of times a participant must change seats is measured at the end of assessing each participant

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

1. Ease of use is rated by investigator using a questionnaire designed for the purpose of this study at the end of assessing each participant
2. Space taken up by prototype device versus conventional devices is assessed once at the start of the trial

### **Completion date**

30/09/2016

# Eligibility

## Key inclusion criteria

1. Registered, returning customers attending the optometry practice for a routine, full NHS or private eye examination, during the trial period
2. Aged between 13 and 45 years
3. Visual acuity (VA) in each eye better than 0.1 logarithm of the minimum angle of resolution (6 /7.5) as determined from their previous records or during the eye examination

## Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Mixed

## Sex

All

## Key exclusion criteria

1. New customers attending the optometry practice for the first time
2. Patients attending for any other kind of optometric appointment other than a full eye examination
3. Those requiring significant adaptations to the standard subjective refraction process used in the eye examination, due to mental capacity/language. This includes the need to measure vision with picture or symbol charts rather than a letter chart
4. Individuals who do not exhibit normal binocular vision (ability for the two eyes to work together), including:
  - 4.1. Subjects who report double vision as a symptom during the eye examination
  - 4.2. Subjects who are found to have unstable binocular vision during the eye examination requiring the prescribing of exercises or prisms
  - 4.3. Individuals with a history of lazy eye (amblyopia), suppression of vision in one eye and/or squint (turn in the eye) as recorded in their previous clinical records, or identified during the eye examination
5. Individuals with any ocular pathology or history of ocular surgery, including conditions known to affect the accuracy refraction measurements (media opacities)
6. Vulnerable subjects – will not be recruited on the basis that they would normally undergo a modified rather than the eye examination, adapted to meet their needs

## Date of first enrolment

02/08/2016

## Date of final enrolment

31/08/2016

# Locations

## Countries of recruitment

United Kingdom

**Study participating centre**  
Community optometric practice  
Sale  
United Kingdom  
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## Sponsor information

**Organisation**  
Topcon Eye Care Company

**ROR**  
<https://ror.org/03fevzd03>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Topcon Eye Care Company

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Habitual Qualitative and Quantitative Physical Activity in Multi-Morbid, Older Persons with Cognitive Impairment	16/12/2020	29/11/2022	Yes	No
<a href="#">Other publications</a>	feasibility sub study	13/02/2020	29/11/2022	Yes	No