Assessment of the Accuracy and Repeatability of the VisionApp – Refraction and Presbyopia Measurement Protocol

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Assessment of the accuracy and repeatability of the VisionApp Refraction, and Presbyopia measurement protocols

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0.0 Background & Rationale

Recent Android mobile device technology is available which allows user-measured refractive error and reading add power. This technology could be quite useful to the clinical and research community. The current study aims to evaluate the accuracy, repeatability, and reproducibility of one such technology by VisionApp.
VisionApp is an app which runs on a smartphone or other device which uses the distance between the user's face and the phone to determine refractive error, while the user looks at different targets (lines, letters, words, etc).

1.0 Objective(s)

1.1 Primary Objectives

Assess the accuracy and repeatability of the mobile app VisionApp for each of its three functionalities compared to standard clinical measures of refraction:

1. Myopia check (using real or simulated myopes with trials lenses)
    a. When a reference refraction is known
    b. When refraction is unknown
2. Presbyopia
    a. reading glasses power as determined by near point
    b. reading addition power as determined by near point

2.0 Outcome Measures/Endpoints

2.1 Primary Outcome Measures

Monocular measurements obtained with VisionApp will be compared to monocular clinical measures. Within a session, repeated measures will be taken for each refraction technique with various over-corrections to simulate different refractive errors. Repeated sessions of this measurement procedure will be performed at 3 separate visits.

1. Spherical equivalent refractive error in diopters will be compared between Myopia Check and the traditional refraction.
2. Presbyopic near point (cm) will be measured in compared with the VisionApp technique and that using a card and ruler, BCC, NRA/PRA, and patient preference.

2.0 Eligibility Criteria

2.1 Inclusion Criteria

A subject is eligible for inclusion in the study if he/she:

- Is at least 18 years of age and has full legal capacity to volunteer.
    - Myopic Subgroup – 18+ years of age, not wearing a near add correction
    - Presbyopia Subgroup - $\geq$40 years of age and currently wear a near add correction.
- Has a refractive error between Plano and -5.00 D of sphere and cylinder components combined.

- Has read and understood the informed consent letter.
- Has had a self-reported oculo-visual exam in the last 2 years.
- Has best-corrected visual acuity of at least 20/20 in each eye
- Is not amblyopic or has any diagnosed ocular disease
- Is willing and able to follow instructions and maintain the appointment schedule.

2.2 Exclusion Criteria

A subject will be excluded from the study if he/she:

- Has any systemic disease affecting ocular health and visual acuity
- Is currently using any systemic or topical medications that could affect ocular health and visual acuity
- Is participating in another eye related research study.

4.0 Study Design

The study will involve 3 visits, each between 1 day and one week apart.

3.0 Enrollment/Randomization

Subjects will be enrolled at the Clinical Optics Research Lab at Indiana University.

Up to 60 participants will be enrolled.

Testing order will be randomized based on a pre-determined pseudo-randomization design.

4.0 Study Procedures

Three repeated measures will occur within a session, and sessions will be held on 3 different daily visits (each separated by 1-7 days).

The following procedures may be done at each visit:
History Demographic and health/ocular history information collected by oral history or measurement using standard clinical tools

Standard Clinical Testing: standard clinical testing including refraction (check of glasses prescription), auto-refraction or abberrometry. Visual acuity and room lighting checks may also be measured using standard clinical techniques

Myopia Check – using VisionApp:
The subject will look at a phone running the VisionApp program set at a particular distance (calibration) and then be instructed to move further from, or closer to the phone, until a given target (letter, lines, patterns, etc) are more or less clear.
This may be done with the subject's own glasses/contact lenses on, or with no glasses/contact lenses on, or while wearing lenses on top of their naked eye, or on top of their own glasses/contact lenses.
Each test may be repeated until at least 10 good data points are collected. This may be done on the right eye, left eye, or both eyes.

We will aim to perform all testing using only spectacle lenses. However, if it proves difficult for the device's native facial recognition software to register the eyes while wearing spectacles, it may be necessary for the investigator to instead utilize soft contact lenses to adjust the eye's correction.
The study doctor will look at the health of the subject's eye with a microscope (a standard clinical ocular health examination) before and after wearing the lenses, to ensure they do not harm the eye. Any lenses utilized will be commercially available, FDA approved lenses. Any lenses will be inserted and removed by a trained professional, and only worn in the office. Subjects will not take any lenses home or wear them outside of the office.
In the case the investigators need to use contact lenses, this will be discussed with the subject and they will get to choose if they want to continue in the study and wear contact lenses, or discontinue.

Presbyopia Check – using VisionApp (only for subjects >40 years of age):
The subject will look at a phone running the VisionApp program set at a particular distance (calibration) and then be instructed to move further from, or closer to the phone, until a given target (letter, lines, patterns, etc) are more or less clear.
This may be done with the subject's on glasses/contact lenses on, or with no glasses/contact lenses on, or while wearing lenses on top of their naked eye, or on top of their own glasses/contact lenses.
Each test may be repeated until at least 10 good data points are collected. This may be done on the right eye, left eye, or both eyes.

5.0 Reportable Events

Reportable events such as protocol deviations and adverse events will be reported to the IRB according to their reporting guidelines.

Adverse event monitoring will begin at the time of consent.

Classification	Definition
Serious Adverse Event	Those events that are life-threatening, or result in permanent impairment of a body function, or permanent damage to a body structure or necessitate medical (therapeutic) or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
Significant Adverse Event	Those non-serious adverse events that occur with contact lens usage that are not sight-threatening but are usually symptomatic and may warrant therapeutic management and /or temporary or permanent discontinuation of contact lens wear.
Non-Significant Adverse Events	Those less severe non-serious adverse events that occur with contact lens usage that are not sight-threatening, may or may not be symptomatic and may warrant palliative management, such as ocular lubricants or temporary interruption of contact lens wear.
Unanticipated Adverse Device Effect	Adverse events in a clinical trial that were not previously identified in the protocol in terms of nature, severity, or degree of incidence. An Unanticipated Serious Adverse Device Effect is an unanticipated adverse event that is serious in nature and caused by or associated with the device and is considered reportable.

6.0 Data Safety Monitoring

The PI will monitor the recruitment, accrual and retention of the subjects as well as the data quality, procedures designed to protect the privacy of subjects, outcome and AE data, results of related studies that may impact study safety, and finally, asses scientific reports or therapeutic development.

7.0 Study Withdrawal/Discontinuation

If a subject decides to participate in this study, they can change their mind and decide to leave the study at any time in the future. The study team will help them withdraw from the study safely. If they decide to withdraw, they will contact the investigators at 812-855-5500 or CORL@iu.edu such that they can take the steps necessary to safely exit them from the study.

8.0 Statistical Considerations

Since this is a pilot stage, exploratory feasibility clinical investigation, there are no pre-specified statistical hypotheses.
This is a pilot stage, exploratory clinical investigation, therefore a formal sample size calculation has not been conducted.
Summary statistics will be produced (e.g. mean, standard deviation) for the refractive error and mixed model analyses will be performed.

9.0 Statistical Data Management

Primary data will be collected paper or electronically and stored electronically in REDCap or in a OneDrive folder (or equivalent). The storage location will be backed up automatically. Quality assurance steps will include: 1) built in range checks; 2) testing of database by study team prior to moving to production mode. The following quality control methods will be used: 1) double entry of data; and 2) extraction and cleaning of data that will be used for analysis every 3 months

10.0 Privacy/Confidentiality Issues

The risk of loss of confidentiality will be minimized by making sure the paper data is properly secured in locked cabinets. Electronic data (from clinical instrumentation) will be saved on the IU OneDrive system (or equivalent). Data will be entered into RedCAP an IU sponsored data management system. Only members of the study team will have access to subjects' identifiable data. In addition to the confidentiality protections above, subject screening and participation will occur in private exam lanes.

11.0 Follow-up and Record Retention

Records will be retained for 7 years as required by Indiana state law.