Clinical Investigation of the VR-800 Device:
Study Protocol

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TITLE: Clinical Investigation of the Vision-R800 Device. Understanding the Value of High Precision Refractions and Lenses to Optometrists and Patients.

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RATIONALE AND SIGNIFICANCE:

While all health care may make patients nervous, the optometric examination can be particularly stressful for patients. There is no wonder with the typical exam combining a 'vision test' as well as the general health examination wherein 'bad news' might be expected. Healthcare anxiety has been associated with poor attention (Taylor, 1986) and reduced satisfaction (Court, 2009); the refraction portion of the optometric examination is particularly subject to these problems.

Poor attention to detail during the refraction may contribute to erroneous results. The subsequent glasses are a constant reminder of the quality of the patient's most recent eye examination (indirectly the quality of the optometrist), as patients view their world through the glasses everyday. The stakes are high when the refraction is taking place for the patient to 'answer correctly' and get a good glasses prescription. The presence of healthcare anxiety as related to optometric examination and refraction can result in wasted healthcare resources.

Furthermore, the technology of the phoropter used during the refraction, as well as the precision of glasses made from the prescription, has remained stagnant over the last century while the optics world has improved exponentially. Lenses with precise optics can now be potentially affordably and reliably produced, and technology in the phoropter can be updated to customize refractions to reduce their length and resulting apprehension.

The Vision-R800 phoropter was developed to give the patient a more precise correction of their ametropia during both the refraction and in their resulting glasses prescription. Furthermore, the advanced technology utilized in the Vision-R800 aspires to deliver a more enjoyable patient and doctor experience in determining a glasses prescription.

AIMS:

In an attempt to quantify the value of high precision refractions and lenses to optometrists and patients, as well as understand the technology of the Vision-R800 machine, the specific goals of this study are:

- Quantify the reliability, repeatability, and efficiency of the Vision-R800 phoropter
- Subjectively and objectively compare the refraction experience for the optometrist with the Vision-R800 phoropter as compared to a traditional refraction, from training through prescription writing
- Subjectively and objectively compare the refraction experience for the patient with the Vision-R800 phoropter as compared to a traditional refraction.
- Quantify the value of high precision glasses, in terms of subjective and objective optical performance.

STUDY DESIGN:

This study is a randomized, bilateral, cross-over dispensing study of the full patient experience/process as would occur in the private practice setting, including the refraction and spectacle dispensing. Specifically, "patient" subjects are randomized to experience the traditional refraction and glasses dispensing (0.25D step lenses) or the Vision-R800 refraction and precision glasses (0.01D step lenses). Patient expectation and experience will be gathered prior to, during, and following the experience and lens use. The doctors will be part of the team of investigators. This investigation will run concurrently to phases one and three.

Vision-R800 Machine Details:

The Vision-R800 phoropter systems have been installed in two 4meter exam lanes at the IU School of Optometry.

For all phases of the study, the optometrists will be asked to refract using the "Smart Exam" algorithm with a few minor modifications. First, steps 14 and 15 (binocular vision and stero) will be removed.

For presbyopes, following testing of distance visual acuity, the algorithm will test JCC and near visual acuity with the add after all of the above distance testing.

Following the refraction, the prescription will be converted from 4 meter testing to infinity using the Vision-R800 conversion equation.

Evaluation of Patient Experience (IU experienced doctors refract naive subjects in a crossover dispensing):

Phase two will consist of a new group of naïve patients. A total of 120 patients will be grouped into single vision and progressive addition wearers. Sixty subjects will be included in each of the single vision and presbyopic lens categories, with 30 trying the traditional refraction process and lenses first and 30 trying the new refraction process and lenses first.

1. Young adults: 19-35 years of age
2. Presbyopic adults: 36-80 years of age, progressive addition lens wearers

Following informed consent, the patient will be asked demographic and other subjective/baseline questions about their past experience with refraction and glasses dispensing(s), as well as expectations. These may be video recorded verbal conversations or paper questionnaires. Subjects may be given a wearable heart rate monitor for the remainder of the procedures.

Patients will be randomized to experience either a traditional refraction or a Vision-R800 refraction performed by a study team member (optometrist). The starting point will be the patient's habitual prescription. The refraction will be audio/video-recorded. A final prescription will be generated. Following the refraction, subjective feedback will be obtained.

Patients will be presented with a frame board (of standard, Luxotica frames) and asked to choose a frame. The necessary fitting measurements and adjustments will be made. Spectacle lenses will be manufactured for this frame using prescriptions from either the traditional refraction or the Vision-R800 refraction.

Upon arrival and verification of the edged and assembled glasses, patients will be presented with their spectacles. Spectacles will be dispensed by an experienced optician. At dispensing and at a two-week follow-up visit, subjective and objective vision testing will be completed. Subjects will be asked to wear their glasses at least 6 hours per day.

Subjects will then be randomized to the other type of refraction and all testing procedures will be repeated. All frames and lenses will be provided by the Sponsor. Between the ordering of the second pair of glasses and their dispensing, subjects will be asked to wear their habitual spectacles.

At the final visit, an investigator will show the patient the following prescriptions, in a randomized order, via the Vision-R800 phoropter, and record visual acuity and subjective ratings, while keeping the patient masked. Finally, the patient will be asked their preference for each prescription in paired comparisons, both monocularly and binocularly.

1. Habitual glasses prescription
2. Traditional refraction prescription
3. Vision-R800 refraction prescription

Primary Outcome Measures:

- Test potential claims with patients, as measured by subjective questionnaires
- Assess the benefits of the full Vision-R800 experience from refraction to lenses to the patient, as measured by subjective questionnaires

Other Outcome Measures:

- Vision quality assessments with traditional refraction and Vision-R800 refraction, as measured by visual acuity and subjective vision ratings

Participants:

Enroll up to 128 to finish 120 subjects, equally split into the below groups:

Young adults: 18+ years of age, single vision glasses wearers

Presbyopic adults: 40-70 years of age, progressive addition lens wearers

*each arm will be targeted to be age, sex and spherical Rx matched, although this is not a requirement

Other subject criteria include:

Not have taken part in other phases of this study

Free of eye disease with an impact on visual acuity or binocular vision abnormalities (by self-report)

The Presbyopic adults must be current adapted progressive addition lens wearers, and the other subject age groups must not be wearing progressive addition lenses.

No formal training in optometry, vision science or in the eyecare field

Must have a wearable pair of glasses from a prescription $\leq$ 2 years old

Must wear glasses at least six hours per day over the last two weeks, and willing to continue wearing glasses at least six hours per day throughout the study

OUTCOME MEASURES:

To achieve the aims outlined above, the outcome measures for this study are broken down into four groups based on where the data is obtained: Patients, Optometrists, Vision-R800 Phoropter and the Glasses.

PATIENTS:

BACKGROUND:

- Personality Type/attention to detail
- Early adopter to technology (type/age of cell phone?)
    - Would your friends describe you as tech savvy (likert)
- Last eye exam, exam experience
- Age of habitual glasses and where they were purchased
- Current satisfaction with habitual glasses prescription
- Pre-exam expectations
- Habitual prescription including pupillary distance (via lensometry)

DURING REFRACTION:

- Stress/comfort (heart rate, subjective questions, observations from video)
- Casual conversation (observations from the video)
- Step-size of refraction, as calculated by algorithm

AFTER REFRACTION:

- Subjective feedback
    - Overall satisfaction with refraction; likes and dislikes
        - Was there any sort of learning curve with how to respond?
        - Stress level/comfort during refraction
        - How does this compare to what you've had done in the past?
    - Level of confidence with prescription (5-point likert), comments
    - Quality of the refraction (5-point likert), comments
    - Likelihood to purchase glasses from refraction (5-point likert), comments *(following both refractions)*
    - Subjective preference (traditional refraction, Vision-R800 refraction)
        - Overall satisfaction with refraction (5-point likert), comments
        - Stress level/comfort during refraction (5-point likert), comments
        - Level of confidence with prescription (5-point likert), comments
        - Quality of refraction (5-point likert), comments
    - Do you feel the Vision-R800 refraction provides better eyecare? (5-point likert), comments
    - Would you seek out an optometrist with this technology? (5-point likert), comments
    - Do you feel that the lenses manufactured from this technology would be more valuable? (5-point likert), comments

    - Did the introduction to this concept live up to your expectations?
    - Did you like the technology the doctor had?
    - Overall, did you prefer one experience overall?
- Perception of the field of view (no question will be asked about this, and it will not be mentioned; instead it will be noted if this is mentioned in the comments from the participant)
- Monocular and binocular preference between Habitual Rx, traditional refraction endpoint, Vision-R800 refraction endpoint (done by investigator, with subject remaining masked to prescriptions)
- Agreement of quality observed in simulation inside Vision-R800 phoropter versus outside world

VISION-R800 PHOROPTER:

- Final prescription given (traditional refraction vs. Vision-R800 refraction algorithm endpoint and doctor's endpoint)
    - Visual acuity with prescriptions
    - Quality of vision with prescriptions
    - Preference with prescriptions
- Repeatability
    - Within doctor (repeatability of endpoint)
    - Between doctor
    - Improvement with number of refractions completed?
- Path of refraction (what lens choices were given)
- Sensitivity of subject to lens changes (0.25D vs 0.01D)
- Efficiency of algorithm (how many questions were asked)
- Length (time)
- Education level required to do the refraction
- Objective refractions versus subjective refractions

GLASSES:

AT DISPENSING AND FOLLOW UP:

- High Illumination, high contrast logMAR Visual Acuity
- Subjective Questionnaires
    - Quality of vision ratings
    - Glare ratings
    - Halos ratings
    - Ghosting ratings
    - Preference compared to habitual lenses (or control lenses)
- Agreement of quality observed in simulation inside instrument versus outside world

STATISTICAL ANALYSIS:

Repeated measures ANOVA and mixed effects regression models will be used to analyze both the main and interaction effects of outcome measures

PUBLICATION PLAN:

Publications may be prepared at Sponsor's request and expense in accordance with the contract.

REFERENCES:

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