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Study Title: *Accommodative Behaviors in Multifocal Contact Lenses*

NCT Number: 06064617

Date of Document: Approved by IRB on Nov 30, 2023, Uploaded to Clinical Trials.gov on 08/18/2025

Research Protocol

Accommodative Behaviors in Multifocal Contact Lenses

Study Objectives:

The purpose of this study is to determine if accommodation differs with center near and center distance multifocal contact lenses

Background and Rationale:

Soft multifocal contact lenses are used for a variety of reasons in patient care. Multifocal contact lenses are most often used to correct presbyopic vision by providing a range of clear vision at both distance and near (Chu and Huang, 2010). Multifocal contact lenses correct vision at different distances by introducing a power gradient over the eye. They are designed using center near or center distance designs. For center near designs, the near addition is place in the center of the lens, and the power becomes more negative in the periphery. Conversely, for center distance designs, the distance prescription is placed in the center, and the power of the lens becomes more positive in the periphery in order to provide the near addition. Center near and distance designs have varying advantages and disadvantages for presbyopic vision correction, so a fitter may choose a specific design based on a patient's individual visual needs. Generally, it is thought that center near designs provide the most accommodative relief and superior near vision because the near addition is centered in the pupil and able to allow maximum near correction, even with miotic pupil size changes associated with accommodation.

There is growing use of soft multifocal contact lenses to slow the progression of myopia in juvenile populations (Walline, Walker, Mutti, et al., 2020). When used for myopia management, the power gradient of a soft multifocal contact lens is utilized to, hypothetically, alter how light focuses in the eye and influence eye growth. Specifically for myopia management, center distance multifocal designs are used. A center distance contact lens optically corrects for the distance refraction in the center of the lens (providing a clear distance image to the macula) while the peripheral portion, with its increasing plus power, generates myopic peripheral defocus. This change in peripheral image focus is thought to provide an optical "stop" signal for axial elongation and myopic progression (Berntsen and Kramer, 2013; Ticak and Walline, 2013; Walline et al., 2020). For myopia management, therefore, multifocal contact lenses are not being used to correct vision or influence accommodation. There have been conflicting reports as to how/if children accommodate normally while wearing multifocal contact lenses. (add some citations here, probably similar to below)

Plus lenses, or add powers, in spectacles are often used in the management of accommodative and binocular vision disorders (Scheiman and Wick, 2008). An add power, or plus lens, relieves accommodative demand. There is conflicting evidence on

whether the add power in soft multifocal contact lenses can be used to manage accommodative and binocular vision disorders (Gong, Troilo and Richdale, 2017; Jimenez, Durban and Anera, 2002; Kang, Fan, Oh, et al., 2013; Madrid-Costa, Ruiz-Alcocer, Radhakrishnan, et al., 2011; Tarrant, Severson and Wildsoet, 2008). Some case reports demonstrate benefits of multifocal contact lenses in accommodative insufficiency and convergence excess but the evidence is not clear and many previous studies utilize lenses that are not readily used anymore (Rodgin, 2009; Weissman, Barr, Harris, et al., 2006). Studies show that soft multifocal contact lenses alter accommodation in participants who wear lenses, but most studies use center-distance lens designs, which is the most commonly used lens for myopia management (Gong et al., 2017; Madrid-Costa et al., 2011; Tarrant et al., 2008).

Most studies that have evaluated accommodative ability and function while wearing soft multifocal contact lenses have examined center distance lenses. Because center distance lenses are used for myopia management, the interest has been to determine if children maintain normal accommodative function while wearing the lenses. Accommodative function while wearing center near lenses has likely not been studied often because these lens designs are used most in presbyopic populations who have no or waning accommodative ability and are using the lenses, specifically, to account for that accommodative inability.-Knowing how spectacle lenses with add powers effectively treat some binocular vision and accommodative disorders and understanding how center near multifocal contact lenses correct presbyopic vision, it is reasonable to hypothesize that center near multifocal contact lenses may provide a greater therapeutic effect for accommodative and binocular vision disorders than center near designs because the central portion of the lens is the addition power, unlike the center-distance lens designs. This study will aim to determine how accommodative function varies with center distance and center near multifocal contact lenses.

Procedures:

Research Design

This study will be an observational single-center investigation using a cross sectional design and each subject will undergo two test sessions.

Sample

The sample size necessary for this study is 20 subjects. The sample size calculation was completed using effect size with standard deviation values from previously published objective accommodative difference between center-distance multifocal contact lenses and single vision contact lenses, which found about 1.0 D ± 0.53 D difference (Gong et al., 2017). In order to detect a 0.5 D difference in accommodative amplitude between center-distance and center-near contact lenses with 90% statistical power, a sample of 14 participants is required. Because a study investigating this hypothesis has not been performed in the past, we will enroll an additional 6 patients to account for unknown variability in the data.

Eligibility Criteria are:

- Ages 18 to ≤ 30 years old
- Acuity of 20/25 or better in both eyes with habitual contact lens prescription
- No history of ocular disease or active ocular inflammation
- No history of ocular or refractive surgery
- No current history of rigid contact lens wear
- Astigmatism ≤1.00 D
- Free of binocular vision disorder (strabismus, amblyopia, vergence dysfunction, accommodative dysfunction)
- No prior or concurrent participation in myopia control or use of low dose atropine, multifocal contact lenses
- No use of any medications suspected to affect accommodation

If a subject presents with conditions such as uncorrected refractive error or pathology, an appropriate referral will be made.

Potential participants will be recruited in the following manners:

- Word of mouth by the investigators among employees and visitors to the College of Optometry
- Flyers
- Email announcements distributed to the faculty, staff, and students at OSU
- Electronic advertisement in the OSU Healthbeat
- Phone calls to potentially eligible participants who are identified from a review of clinical records at the College of Optometry to identify those who wear soft contact lenses.

Measurement

The primary measurement of interest is accommodation, which will be quantified using the following techniques:

Objective Accommodative Amplitude: This non-invasive technique quantifies the total focusing ability of the eye using methods that are commonly used clinically. The refractive power of the eye will be measured with the Grand Seiko autorefractor (a commercially available instrument) while study participants view a 20/30 sized letter at multiple stimulus positions (ranging from optical infinity to 20cm). Ten repeated measures will be collected at each stimulus position. For all measurements, participants will wear an eye patch over their left eye and view the letter target with their right eye while keeping their chin in a chinrest and forehead against the forehead rest. The Grand Seiko autorefractor uses infrared light to obtain refractive measures of the eye and the procedure is non-invasive. The following distances are where accommodation will be assessed:, 2.5 D (40 cm), and 4 D (25 cm), and 5 D (20 cm). Because multifocal contact lenses can interfere with the optics and readings of an autorefractor, the multifocal will only be worn on the left eye during this testing. The patient's habitual

contact lens with distance only will be on the right eye. An infrared wratten filter will be placed over the right eye, so that the left eye (with the multifocal) will influence accommodation and readings can be obtained from the right eye.

Subjective Accommodative Amplitude: This technique quantifies the nearest position of clear focus using a method that is the standard technique used in a routine eye examination whereby the participant will be asked to view a row of 20/30 letters first held in close proximity to the eye (approximately 2-3 cm) and then pulled away from the eye along a near point rod. The participant will be instructed to report the moment when the letters first become blurred. The measurement will be repeated three times and averaged and the individual findings compared to published age norms for classification of reduced or adequate accommodative amplitude (Hofstetter, 1944).

Accommodative Accuracy: This technique determines the accuracy of the eye to focus at a near viewing distance. A handheld light and loose trial spectacle lenses are used to quantify the focusing position of the eye while the participant views letters printed on a card. The lenses are held in front of the participant's eye and the light shown quickly across the eye from arm's length.

Accommodative Facility: This technique determines the ability of the eye to quickly focus and relax, which is often needed for visual demands in a classroom. Participants will view a 20/30 letter at 40 cm. The examiner will then place ±2.00 D flipper lenses in front of the patient's eye (plus or minus). Once the participant clears the letters, they will state "clear" and the examiner will flip to the other side. The number of flips per minute will be recorded.

Detailed Study Procedures

The study will enroll 20 participants from 18-30 years old. The study consists of two days of office visits to the OSU College of Optometry (a baseline visit, and then a second visit on another day with center-distance and center-near contact lenses). Participants will complete the study visits in the Fry Hall clinic research Lab.

<u>Baseline Exam:</u>

- Questions regarding participant demographics, medical history, ocular history, medication use, and refractive error (glasses and contacts) if known.
- Visual Acuity – participants identifying letters to assess visual acuity at <u>distance</u> and <u>near</u>.
- Contrast Sensitivity – participants identifying letters to identify contrast sensitivity at 50 cm.
- Pupil Size – determination of pupil size using a ruler to measure diameter in millimeters in light and dark.
- Ocular alignment:
    - Cover Test - participants viewing a letter or picture while an investigator covers the eyes with a cover paddle and assessed eye alignment.

    - Modified Thorington - Measured at distance and near.
- Near Point of Convergence – participants viewing letters while they are moved closer to the eyes to assess convergence movements.
- Stereopsis – participants wearing 3D glasses and identifying shapes in a book to assess depth perception.
- Accommodation - Measures of accommodation will be performed in the following order using the protocols described above under "Measurements":
    - **Push-up method -** Accommodative amplitudes of accommodation will be measured in the right eye only, 3 times.
    - **Monocular estimation method (MEM) -** This will be measured at 40 cm, in the right eye only.
    - **Accommodative Facility -** Accommodative facility (in cycles/minute) will be measured with ±2.00 D flippers in the right eye only and binocularly.
    - **Grand Seiko WR-5100K** – Refractive Error will be measured at several points:
        - 0 D (distance)
        - 2.5 D (40 cm)
        - 4 D (25 cm)
        - 5 D (20 cm)
- Refractive Error Assessment – Non-cycloplegic central refractive error (with and without contact lenses). Non-cycloplegic refractive error will be assessed with the Grand Seiko WR-5100K. This will be done with and without Biofinity sphere contact lenses (that is the same prescription as the participant's habitual contact lens prescription). An average of 10 readings will be calculated (both with and without habitual correction).
- Dilation – participants will be dilated with 1% tropicamide. They will receive 2 drops, 5 minutes apart.
- Cycloplegic Central Refractive Error (without contact lenses). Cycloplegic refractive error will be assessed with the Grand Seiko WR-5100K. This will be done without contact lenses on. An average of 10 readings will be calculated.

<u>Second Visit</u>

- At the second visit, participants will repeat measurements completed at the first examination (except for dilation/cycloplegia) with a <u>center-distance</u> and <u>center-near</u> Biofinity multifocal contact lens (both with +2.50 D add). The order will be randomized for each participant. The multifocals will be worn binocularly for all testing except for autorefraction, so that the optics of the contact lenses will not interfere with measurements.

The total time for each study visit will be no more than 90 minutes.

<u>Study Risks</u>

The risks involved with the participation of this study are no greater than that incurred in a routine eye exam with dilation. The side effects that participants might experience are blurred vision (that generally affects near viewing more than distance), and light sensitivity. Previous studies suggest that the side effects of both concentrations are minimal and do not impede activities of daily living. These drops will only be instilled one time at one visit and side effects should wear off within 4-6 hours. All other study procedures are non-invasive and only involve lights as the participant places his/her chin on a chinrest and looks straight ahead.

Data Collection and Participant Confidentiality

Data will be collected on a paper study form that includes only the participant's study ID. Study measures obtained with the autorefractor will be printed from the instrument and the participant's study ID written on the print-out. The print-outs will then be taped to the paper study form and later scanned into pdf format for storage on the Investigator's computer. No personally identifying information will be stored on the paper datasheet, or in the generation of the scanned pdf. Signed consent/assent/parental permission documents will be kept separate from the study data sheet in a binder in the Investigator's locked laboratory, accessible only to the study team. The link between the study ID and the participant's personal information will be maintained on the signed consent documents.

Internal Validity

There are no threats to internal validity. All procedures performed in the examination are standard procedures that have been performed frequently in other studies. While this project is assessing measurements in one population, there is limited threat to external validity because this is a project of instrument comparability and repeatability and is not intended to make generalizations about the population as a whole.

Data Analysis

Repeated measures analysis of variance (Repeated measures ANOVA) will be completed with measurement environment (single vision CL, center-distance CL, center-near CL). If differences are detected in lens type (center-distance, o center-near), a post-hoc analysis will take place.

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