MYOPIA TREATMENT STUDY (MTS1) PROCEDURES MANUAL

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EYE DROP QUESTIONNAIRE

Eye Drop Questionnaire

Required Equipment

- Eye drop questionnaire

Procedure

1. The questionnaire is completed by the child (not by the parent), either on paper or online via REDCap.
2. The questionnaire may be either completed directly by the child or administered by office staff that are not masked to treatment group.
3. The child should complete the questions based on their experience with eye drops since the previous visit.
4. If a question does not apply, then the child should select "Never".

EYE DROP QUESTIONNAIRE

Questions are completed by the child about their experience with eye drops since the previous visit. If the child is unable to answer the questions, or if the question does not apply, select never.

THESE QUESTIONS ASK IF CERTAIN THINGS ARE HARD FOR THE CHILD

1. Do you hate eye drops?
□ Never □ Sometimes □ Most of the time □ All the time

2. Do your eye drops hurt your eyes?
□ Never □ Sometimes □ Most of the time □ All the time

3. Do you have a hard time seeing?
□ Never □ Sometimes □ Most of the time □ All the time

4. Do you have trouble reading up close?
□ Never □ Sometimes □ Most of the time □ All the time

5. Does bright light make it hard for you to do things outside?
□ Never □ Sometimes □ Most of the time □ All the time

THESE QUESTIONS ASK IF THE CHILD IS BOTHERED BY CERTAIN THINGS

6. Are you bothered by how your eye drops make your eyes look?
□ Never □ Sometimes □ Most of the time □ All the time

7. Does it bother you because your eye drops hurt your eyes?
□ Never □ Sometimes □ Most of the time □ All the time

8. Does it bother you because you have a hard time seeing?
□ Never □ Sometimes □ Most of the time □ All the time

9. Does it bother you because you have trouble reading up close?
□ Never □ Sometimes □ Most of the time □ All the time

10. Does it bother you because bright light makes it hard to do things outside?
□ Never □ Sometimes □ Most of the time □ All the time

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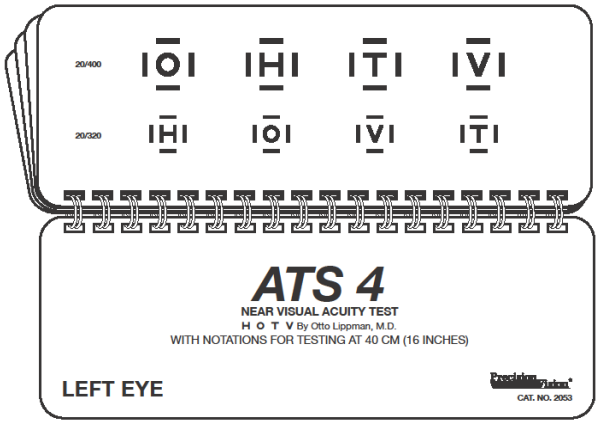
BINOCULAR NEAR ACUITY TESTING

ATS4 Binocular Near Acuity Testing

Required Equipment

- ATS4 Near Acuity Test



Description

The ATS4 Near Acuity Test (Precision Vision, Cat No. 2053) consists of a series of flip cards with lines of single-surrounded HOTV optotypes from 20/400 to 20/20 in 1-logMAR line intervals. A matching card is attached so that the child can either verbalize his/her response or point to the HOTV letter on the matching card. The individual administering the test may point to the optotype to be named.

Specifications

The testing distance is 40 cm (measured with string attached to test).

- If the child cannot reach the attached matching card, place the laminated HOTV matching card in the child's lap so that he or she may point to the letters on it to avoid the child leaning in closer than the 40 cm distance to point to the letters.
- The test is performed binocularly with optotype set #1.

Procedure

Screening phase: Ask the patient to identify the first HOTV optotype at the 20/100 level. The individual administering the test may point to the optotype to be named. If the first letter is correct, the next smallest logMAR optotype size is shown. This process continues through 20/20, asking the patient to identify only the first letter on each acuity level until the patient gives an incorrect response.

Threshold phase: Begin testing 1 acuity level above where the patient gave an incorrect response (i.e., last line with correct optotype identification) during the screening phase. Now ask the patient to identify all 4 letters for that level.

- If the patient identifies either 3 of 3 or 3 of 4 correct, continue to show successively smaller letters until 2 optotypes on a level are missed.
- If the patient was unable to correctly identify at least 3 of 4 correct, test successively larger acuity levels until 3 of 3 or 3 of 4 on a level are correct.

The near visual acuity score is the smallest letter size (line) for which at least 3 presentations (3 of 3 or 3 of 4) are correctly identified.

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BINOCULAR AMPLITUDE OF ACCOMMODATION

Binocular Amplitude of Accommodation

The binocular amplitude of accommodation is a measure of the participant's maximum accommodative ability.

Required Equipment

- Near Point Rule (rod with a moveable target and metric markings) (Gulden Ophthalmics #15150)

Procedure

1. Testing should be done with the participant wearing his/her refractive correction under binocular viewing conditions.
2. Ensure good illumination using ambient and overhead lighting.
3. Hold the Near Point Rule (with single column of 20/30 letters as the target placed at 40 cm on the rule) with edge of rule gently at the level of the participant's brow, centered between the right and left eyes.
4. Slowly move the target toward the participant at approximately 1 to 2 cm/sec beginning at 40 cm from the participant.
5. Instruct the participant to: "Try and keep the letters clear for as long as possible, but tell me when it becomes blurry and you cannot get it clear again."
6. Move the target towards the participant's eyes until the participant reports that the letters are blurred and he/she cannot regain clarity. This will be considered the endpoint.
7. If the participant reports 2 images prior to the becoming blurry, encourage the participant to try and make it single again. If the participant regains fusion, record the point of first sustained blur as the endpoint. If the child does not regain fusion, record the distance where fusion was lost as the endpoint.
8. Measure the near point of accommodation to the nearest half centimeter using the center of the forehead at the level of the brow as the zero measure point. Record in half centimeters.

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CYCLOPLEGIA

Cycloplegia

Required Equipment

- 1% cyclopentolate

Description

Cycloplegia with 1% cyclopentolate

Procedure

1. The use of proparacaine 0.5% prior to cycloplegic drops is at investigator discretion.
2. Place 1 drop of 1% cyclopentolate in each eye.
3. Wait 5 minutes prior to instillation of second drop.
4. Place second drop of 1% cyclopentolate in each eye.
5. Allow 30 minutes ± 5 minutes from the time of the second drop until making measurements requiring cycloplegia.
6. If cycloplegia is incomplete after 30 minutes ± 5 minutes, a third drop of 1% cyclopentolate should be instilled, allowing a further 30 minutes ± 5 minutes from the time of the drop until making any measurements requiring cycloplegia.

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CYCLOPLEGIC AUTOREFRACTION

Required Equipment

- Autorefractor (same autorefractor must be used throughout the participant's study participation)

Cycloplegic Autorefraction

Description

Autorefraction measurements will be obtained using an autorefractor 3 times in each eye with cycloplegia.

Procedure

1. Measurements are obtained without optical correction following cycloplegia, which occurs 30 minutes ±5 minutes from the time of the second drop of 1% cyclopentolate. The use of a timer or electronic medical record with a timer is encouraged.
2. Three measurements at distance (three single initiated measures, i.e., "separate pulls of the trigger," whether individual measures or mean of multiple measures) meeting the instrument's index of sufficient quality are made for each eye (quality index is based on the manufacturer's specification and differ for each instrument).
3. Record autorefraction readings from the printout generated by the autorefractor.
4. Printouts must be saved as part of the documentation process. If the printouts will discolor over time and be illegible, photocopies should be made promptly and marked as official copies.

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AXIAL LENGTH AND OTHER BIOMETRY

Required Equipment

- Optical biometer (LENSTAR or IOLMaster)

Axial Length and Biometry

Description

Axial length and other optical biometry will be measured using an optical biometer 3 times in each eye with cycloplegia. The IOLMaster 500 will not provide a measure of lens thickness.

Procedure

1. Measurements are made following cycloplegic autorefraction, which occurs 30 minutes ±5 minutes from the time of the second drop of 1% cyclopentolate.
2. Three measurements (three single initiated measures, i.e., "separate pulls of the trigger," whether individual measures or mean of multiple measures) meeting the instrument's quality index are made for each eye (quality index is based on the manufacturer's specification and differ for each instrument).
3. Record measurements of axial length, mean corneal radius, anterior chamber depth, and lens thickness (if available) to the nearest 0.01mm.
4. Generate measurement printout for each measure and save these printouts for study documentation. If the printouts will discolor over time and be illegible, photocopies should be made promptly and marked as official copies

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