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Standardizing the Measurement of Visual Acuity for Clinical Research Studies

Guidelines from the Eye Care Technology Forum

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Background

Visual acuity is a ubiquitous measure of visual function that is sensitive to optical, retinal, and neural disorders of the eye. Visual acuity measurement can extend over a wide range and is correlated with the ability to perform many tasks that are important in our society, such as reading or driving. This measurement is often an important endpoint for clinical vision research projects.[1,2] For some studies, such as studies of refractive surgery, it may be relevant to measure high visual acuity scores and analyze small differences within this confined range. For other studies, such as those assessing treatment of proliferative diabetic retinopathy, the full range of visual acuity, including poor visual acuities such as 20/800 or worse, must be evaluated.

To be useful in clinical research, the measurement of visual acuity must be standardized. The following are the major features of the standardized measurement of visual acuity that have evolved as part of 20 years of clinical research. It is recommended that these procedures be used in clinical research projects to help ensure accurate and reproducible assessment of visual acuity.

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Recommended Procedures

- Standardized Visual Acuity Chart (e.g., Bailey-Lovie or Early Treatment Diabetic Retinopathy Study);
- High contrast between optotypes and background;
- Same number of optotypes at each size level;
- Spacing between and within rows proportional to the optotype size;
- Optotypes of approximately equal difficulty (Landolt rings are the standard);
- Logarithmic progression of optotype size;
- Standardized testing conditions;
- Standardized chart lighting (often approximately 160 cd/m^2; range, 80–320 cd/m^2);
- Standardized testing distance (preferably at least 4 m for visual acuity 20/200 or better);
- Standardized procedures for refraction and measurement of visual acuity;
- Consistent refraction procedures;
- Different chart for refraction and final visual acuity measurement;
- Inform examinee that there are only letters, numbers, rings, etc., on chart;
- Standard instructions before reading chart (e.g., do not lean forward, read slowly, guess if unsure, etc.);
- Rules for rereading letters;
- Standard methods for encouraging subjects to guess as the letters become difficult to read;
- Rules for ending examination;
- Standard methods for scoring visual acuity (equal credit is given for each letter correctly read);
- Standard methods for measuring low visual acuity (e.g., rules for decreasing distance between subject and chart and scoring visual acuity if subject's

threshold is not within the range of the chart). To ensure a valid visual acuity measurement, the subject should be able to read four or more of the largest letters and none of the smallest letters. Special scoring methods may be necessary for subjects with thresholds outside the range of the chart or with substantial visual field loss that causes them to miss some letters on all rows.

Previous publications provide examples as to how the above-listed principles have been used to measure visual acuity.[1,2] Deviations from these detailed methods may be reasonable or even necessary for particular studies. If other procedures are used, however, care should be taken to avoid reducing the reliability of the measurements.

A recently published booklet includes additional details.[3] Although this booklet focuses on the assessment of visual function for visual disability, the methods for measuring visual acuity are adaptable to all visual acuity examinations and summarize the National Research Council report on standardization of visual acuity measurements[4] and the incorporation of these standards into those recommended by the Consilium Ophthalmologicum Universale[5] and the International Standards Organization.[6]

Another excellent resource is the protocol for visual acuity measurement used in the Age-Related Eye Disease Study.[7] This protocol is detailed but it does provide guidelines for standardizing refraction procedures and visual acuity measurements within clinical trials. This protocol is also available as part of the revised guidelines on visual acuity measurement at the United States Food and Drug Administration.

References

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