Comparing Ocular Muscle Limitation Tests for Clinical Trial Use

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Objective: To evaluate portable methods for documenting ocular muscle limitation that might be used at multiple sites in a clinical trial.

Methods: In a prospective consecutive case series, 2 examiners independently evaluated 3 methods of ocular muscle duction testing: a grading scale of 0 to −5 that is in clinical use, the Kestenbaum limbus test using a ruler to measure the millimeters of ocular movement, and an adapted cervical range of motion (CROM) device that measures ocular movement in degrees. Twenty consenting patients (mean age, 55 years) with diplopia, 8 with ocular myasthenia gravis, 11 with a cranial nerve III or VI palsy, and 1 with dysthyroid ophthalmopathy were studied.

Results: For Kestenbaum measures, between examiners the standard deviation of the difference for all ductions was 1.9 mm ($r=0.75, P=.01$); 95% of differences were 4 mm or less. For the CROM device, the standard deviation of the difference was 7.1°; 95% of differences were 15° or less ($r=0.73, P=.01$). For each examiner, the CROM standard deviation of the difference was less than 2° ($r=0.98, P=.01$). For the grading scale, the 2 examiners had the same score in 85% of ductions ($r=0.92, P=.01$).

Conclusions: The Kestenbaum test and the CROM device gave similar interexaminer repeatability. The repeatability for CROM measures for each examiner was high but was considerably less between examiners. The grading scale gave similar results between examiners.


**STANDARDIZED OBJECTIVE TESTING is needed to gauge the effect of therapy on ocular motor dysfunction, but specific methods have not been used in a clinical trial. The technique of Urist,1 binocular field testing,2 and Hess screen are not suitable because of low retest reliability, poor correlation with the patient’s visual disability, and the need for a stable area of binocular single vision, which is often absent in a variable disorder such as myasthenia gravis. A photographic system used in the assessment of sixth nerve paresis, although reliable and reproducible, is not portable.3 We assessed 3 methods that are fast, portable, and readily available and might provide measurements of ocular muscle limitation in a clinical trial.**

METHODS

We tested supraduction, infraduction, abduction, and adduction of each eye monocularly by 3 methods: a grading scale4 with 0 for full excursion and −5 for failure to reach the midline (−4 reaching midline, −3 to −1 for excursions in 25% increments); millimeters of excursion by means of the limbus test5; and the degrees of movement measured with an adapted cervical range of motion (CROM) device.6 Wearing the CROM device, a headgear and spectacle frame with gravity-driven meters, the patient fixated on a 20/40 letter as the examiner rotated the patient’s head. When the patient noted optotype blur caused by rotation of the head moving the target off the macula, we recorded the degrees registered on the appropriate meter. Each CROM measure was repeated.

Two examiners independently prospectively tested 20 patients with diplopia caused by unilateral cranial nerve III or VI palsy (11 patients), dysthyroid ophthalmopathy (1 patient), and myasthenia gravis (8 patients) (mean age, 55 years). All patients gave informed consent. The repeatability of CROM measures for each examiner and the standard deviation of the difference for all results between examiners were evaluated by means of Pearson correlation or intraclass correlation coefficient.

RESULTS

For the limbus test results, the standard deviation of the difference for 160 ductions was 1.9 mm ($r=0.75, P=.01$); 95% of differences were 4 mm or less. For the CROM device, the standard deviation of the difference was 7.1°; 95% of differences were 15° or less ($r=0.73, P=.01$). For each examiner, the CROM standard deviation of the difference was less than 2° ($r=0.98, P=.01$). For the grading scale, the 2 examiners had the same score in 85% of ductions ($r=0.92, P=.01$).
tions between examiners was 1.9 mm ($r=0.75$, $P=.01$); approximately 95% of differences were 4 mm or less.

For CROM measures between examiners, the standard deviation of the difference was 7.1°; approximately 95% of differences were 15° or less ($r=0.73$, $P=.01$). For each examiner, the standard deviation of the difference for the repeated CROM measurements was less than 2° for each examiner ($r=0.98$, $P=.01$) (Figure).

For the grading scale, the 160 ductions for each examiner were the same grade in 85% ($r=0.92$, $P=.01$). The grades differed by 1 grade in 25 measures and by 2 grades in 1 measure.

COMMENT

Our results with the CROM device gave a standard deviation of the difference between examiners considerably larger than the 1.1° reported by Kushner. The variability of the results for 2 examiners suggests that neither the limbus test nor the CROM device method as performed in this study is suitable for a clinical trial. In addition, ptosis, poor vision, and bifocal and progressive glasses limit the use of the CROM device. Although the categorical grading system results were consistent between examiners, the coarse determinations may not disclose all clinically relevant changes in a multicenter study. We remain unconvinced that any of these or other existing methods for assessing extraocular muscle limitation or binocular diplopia can be used to determine the effects of therapy, particularly in general ophthalmology or neurology clinics.

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