Medical Policy

Subject:	Eye Movement Analysis Using Non-spatial Calibration for the Diagnosis of Concussion		
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Description/Scope

Concussion, (also known as mild traumatic brain injury), occurs following direct or indirect external trauma to the head that causes a change in brain function. Because there is no single objective measure or combination of measures for diagnosis of concussion, physicians must rely on expert guidelines, available assessment tools and clinical judgment to make a diagnosis of concussion.

Researchers are exploring eye movement analysis that uses temporal (rather than spatial) calibration to aid in the diagnosis of concussion. The EyeBOX® (Oculogica, Inc. [New York, NY]), is the first baseline-free, temporal calibration eye movement analysis device to assist physicians in objectively evaluating individuals with suspected concussion.

Position Statement

Investigational and Not Medically Necessary:

Eye movement analysis using non-spatial calibration is considered investigational and not medically necessary for the diagnosis of concussion.

Rationale

Diagnosis of Concussion

Concussion occurs following direct or indirect external trauma to the head that causes a change in brain function. Concussion can affect a variety of clinical domains: physical, cognitive, and behavioral or emotional. The various neurological signs and symptoms of concussion may be nonspecific, subtle and

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transient, and may persist beyond the usual recovery timeframe. Alterations in balance, as well as cognitive or sensory disturbance, may pre-dispose the affected individual to further injury in the future (Stuart, 2020).

Concussion diagnosis can be challenging because there is currently no generally accepted definition or diagnostic criteria for concussion and no single assessment has been accepted as being able to identify those with a concussion. Most individuals with a suspected head injury are examined using the 15-point Glasgow Coma Scale (GCS). However, the GCS is based on symptoms and is neither sufficiently sensitive to assess cognitive and neuropsychiatric deficits of concussion nor predictive of outcome. In addition to GCS evaluation, an individual suspected of having sustained a concussion will generally also undergo a CT scan of the head to detect brain tissue damage or intracranial lesions, however, a majority of individuals evaluated for concussion do not have detectable intracranial lesions after having a CT scan. Physicians must therefore rely on expert guidelines and available assessment tools and clinical judgment for concussion diagnosis. Availability of a non-invasive, radiation sparing test for concussion will help health care professionals determine the need for a CT scan in individuals suspected of having a concussion and help prevent unnecessary neuroimaging and associated radiation exposure. In recognition of the need for more concise and accurate assessment tools, researchers are exploring the use of eye tracking technology to aid in the diagnosis of concussion.

Association of Oculomotor Dysfunction with Brain Injury

Traumatic brain injury (TBI) can result in a variety of visual disturbances with many individuals exhibiting multiple visual defects in combination with a decline in overall health. Inasmuch as 6 of the 12 cranial nerves (CN) directly bear on the visual process, it is not surprising that numerous symptoms of oculomotor dysfunction might be reported in individuals who have sustained a TBI. Defects in primary vision such as visual acuity and visual fields, eye movement disorders including vergence, saccadic and smooth pursuit movements, and in more complex aspects of vision involving visual perception, motion vision, and visuo-spatial function, have all been reported in TBI. Eye movement dysfunction may be an early sign of TBI (Armstrong, 2018).

Cifu and colleagues (2015) conducted a study to determine whether computerized eye tracking could provide a more objective measure to diagnose and to monitor improvement of symptoms following a concussion. Eye-tracking data, collected via a head-mounted, video-based binocular eye tracker, was used to examine saccades, fixations, and smooth pursuit movement in a group of 60 military service members with postconcussive syndrome and a control group of 26 asymptomatic subjects, in order to determine if eye movement differences could be found and quantified. The diagnosis of concussion was confirmed by the

study physiatrist's history, a review of medical records, and physical examination. Different features of saccades, fixation, and smooth pursuit eye movements were analyzed. Participants with symptomatic concussion I had statistically larger position errors, smaller saccadic amplitudes, smaller predicted peak velocities, smaller peak accelerations, and lengthier durations. Individuals with symptomatic concussion were also less likely to follow a target movement (less primary saccades). Overall, symptomatic concussion tracked the stepwise moving targets less accurately, revealing possible brain dysfunction. The authors concluded that this investigation represents an important initial step in the understanding of the role of both eye movement abnormalities and computerized eye tracking in the diagnosis and monitoring of symptomatic concussion, but additional studies investigating specific linkages between symptoms, eye-tracking abnormalities, and neuropathology are needed.

In 2018 Howell and colleagues presented the results of a cross-sectional and multisite study to measure eye tracking performance of athletes who were diagnosed with a concussion and uninjured controls. Individuals who reported to two tertiary care sport concussion clinics within 10 days of concussion completed an objective eye tracking assessment. Only individuals who sustained a concussion during sports or by a mechanism involving forces similar to sports, such as being injured during recreational activities or falling from ground level, were included in the study. Subjects with more severe injury mechanisms, such as falling from a height or sustaining motor vehicle collisions, were excluded. Researchers identified and recruited healthy adolescent control participants between the ages of 11 and 18 years who were involved in a program at a sports injury prevention center or were children of hospital employees. No spatial calibration was used for tracking eye movement. A total of 79 participants completed the study, 44 with concussion (mean age = 14.1 ± 2.2 years, 39% female) and 35 controls (mean age = 14.3 ± 2.4 years, 57% female). Right eye skew along the bottom of the screen was significantly higher for the concussion cohort compared to controls (median = 0.022 [interquartile range = -0.263, 0.482] vs 0.377 [interquartile range = -0.574, -0.031]; p=0.002), but not the left eye. Among the variables explored, right eye skew was altered for adolescents with a concussion. The authors concluded that the use of objective eye-tracking technology that can quickly identify individuals with vision-specific disturbances after concussion may allow for earlier recognition of deficits soon after injury and allow for earlier specialist referral and intervention. Because participants in this study reported for care after a concussion to one of two specialized sport concussion clinics associated with a regional tertiary care hospital, findings from this cohort of individuals may not be generalizable to other populations of individuals with concussion.

In a 2021 study, Oldham and colleagues reported the results of a study which examined the relationship between self-reported symptoms and concussion-related eye tracking impairments. The study design

included three arms that compared gait performance between (a) adolescents with a concussion who have normal eye tracking, (b) adolescents with a concussion who have abnormal eye tracking, and (c) healthy controls. Eye tracking and gait assessments were completed on a total of 30 concussed participants (age: 14.4 ± 2.2 years, mean ± SD, 50% female) and 30 controls (age: 14.2 ± 2.2 years, 47% female). All eye tracking was binocular, and no spatial calibration was used to allow for the independent analysis of both pupils. The BOX score (a metric of pupillary disconjugacy) was used to quantify oculomotor dysfunction. Symptoms were gathered using the Post-Concussion Symptom Scale (PCSS), and gait speed was measured using triaxial inertial measurement units. The authors reported a significant association between total PCSS score and BOX score in the concussion group (β = 0.16, p=0.004, 95% confidence interval [CI]: 0.06-0.27), but this association was not seen in the control group (β = 0.21, p=0.08, 95%CI: -0.03 to 0.45). No significant associations between PCSS symptom profiles and BOX scores were observed in the concussion or control cohorts. Additionally, there were no significant differences in single-task or dual-task gait speed. The concussed cohort with impaired eye tracking reported higher total symptom severity, as well as worse symptom severity across the five PCSS symptom domain profiles. However, eye tracking deficits did not appear to be caused by any specific symptom domain. The diminished gait speeds in those with abnormal BOX scores was not statistically significant. The authors acknowledged that some of the limitations of the study included study participants being recruited from a regional tertiary care children's hospital. Therefore, the results of the study cannot be generalized to other populations. Additionally, the sample size of individuals with an abnormal BOX score was limited and predominantly female. The authors suggested that future research efforts examine the role of gender differences in eye tracking with a larger abnormal group. Lastly, the researchers did not assess if participants required glasses or corrective devices.

Temporal (Non-spatial) Tracking Device to Detect Concussion

Bin Zahid and colleagues (2020) assessed an automated eye-tracking algorithm as a biomarker for concussion as defined by its symptoms and the clinical signs of convergence insufficiency and accommodation dysfunction. In this cross-sectional case-control study, a total of 56 concussed pediatric subjects and 83 uninjured pediatric controls underwent eye tracking prospectively. Participants were not spatially calibrated to the tracker to allow independent analysis of each pupil position over time. Researchers obtained metrics comparing velocity and conjugacy of eye movements over time and compared them with the correlation between Acute Concussion Evaluation (ACE) scores, accommodation, and convergence. The investigators found that the 12 eye-tracking metrics were significantly different between the concussed and non-concussed cohorts. They observed that a model to classify concussions as diagnosed by symptoms using the ACE had an area-under-the-curve (AUC) of 0.854. The researchers also indicated that an eye-tracking model built to identify near-point-of-convergence (NPC) disability achieved 95.8% specificity and 57.1%

sensitivity for an AUC of 0.810. Eye tracking detected convergence and accommodative abnormalities as well as other types of oculomotor dysfunction associated with concussion. The authors noted that individuals without head injury but with body trauma or other orthopedic injuries were not studied; therefore, it is not known if the results of this study can be applied to individuals without a head injury. Also, the model-building data set consisted primarily of teens, whereas the control subjects in the cross-validation data set were generally older than 20 years of age. This could have led to a higher false-positive rate and a lower sensitivity in the cross-validation data set. Additional studies are needed to clarify whether patterns of eye-tracking abnormalities demonstrated after concussion are age dependent.

The EyeBOX Device to Diagnose Concussion

In 2018, the United States Food and Drug Administration (FDA) granted de novo approval to EyeBOX as the first non-invasive, baseline-free tool directed at diagnosing concussions. The FDA approval letter includes the following indications for use:

- **The EyeBOX is intended to measure and analyze eye movements as an aid in the diagnosis of concussion within one week of head injury in patients 5 through 67 years of age in conjunction with a standard neurological assessment of concussion.**
- **A negative EyeBOX classification may correspond to eye movement that is consistent with a lack of concussion.**
- **A positive EyeBOX classification corresponds to eye movement that may be present in both patients with or without concussion (FDA, 2018).**

During the examination, the EyeBOX displays a 220 second video for the individual to watch. As the individual watches the video, the EyeBOX measures and analyzes eye movements to provide objective data that is used to aid in the diagnosis of concussion. The test generates an aggregate score ranging from 0 to 20 which is referred to as the Box score. A Box score of less than 10 may correspond to eye movement that is consistent with a lack of concussion. A Box score of 10 or greater corresponds to eye movement that may be present in both individuals with or without concussion. Additionally, EyeBOX also generates a report which the physician would use to interpret the validity of the test results.

The EyeBOX test takes approximately 4 minutes to complete and should be performed within 1 week of the head injury. The EyeBOX is not considered a standalone diagnostic test but should be used in conjunction with a neurological assessment and a comprehensive eye exam.

EyeBOX differs from some other tests that utilize eye analysis technology to identify individuals that may have sustained a concussion. Other technologies require a baseline test, which is often completed at the beginning of a sport season, pre-injury, and is compared to subsequent test results at the time of a suspected concussion. However, when evaluating trauma subjects in the emergency room, a baseline concussion assessment is often not feasible. Because the EyeBOX does not require an initial or previous baseline examination results, it differs from the other technologies that utilize eye analysis data to rule out or confirm suspected concussion. Additionally, the EyeBOX technology utilizes temporal (not spatial) calibration, so instead of tracking what an individual is looking at, the EyeBOX tracks and measures how well the eyes move.

In 2015, Samadani and colleagues discussed the challenges in making an accurate diagnosis of concussion or other forms of TBI and highlighted the differences between spatially and non-spatially calibrated eye tracking. Potential applications of the algorithm include improved diagnosis and detection of diseases ranging from internuclear ophthalmoplegia to strabismus, however its greatest initially recognized value is as a potential outcome measure or biomarker for brain injury and concussion. The author stated that the utility of non-spatially calibrated eye tracking will ultimately be determined by researchers and clinicians who will conduct additional clinical trials that demonstrate the value of non-spatially calibrated eye tracking. This article also includes an overview of two other published studies co-authored by this author which are discussed below (Samadani 2015[a]).

Samadani and colleagues (2015c) conducted a study to identify disconjugacy gaze in individuals that had suffered a concussion, regardless of whether the trauma was apparent on brain imaging with CT scan. The researchers prospectively tracked the eye movement of 64 normal, healthy, non-injured control subjects and compared the findings to 75 trauma participants with either a positive head computed tomography (CT) scan (n=13), negative head CT (n=39), or nonhead injury (n=23) to determine whether eye tracking without spatial calibration would identify the disconjugate gaze associated with both structural brain injury and concussion. Tracking metrics were then correlated to a clinical concussion measurement tool (the Sport Concussion Assessment Tool 3 [SCAT3]) in trauma subjects. Five out of five measures of horizontal disconjugacy were increased in positive and negative head CT subjects relative to the noninjured control subjects. Only one of five vertical disconjugacy measures was significantly increased in brain-injured participants relative to controls. Balance testing (Balance Error Scoring System) did not reveal any significant differences in the two brain-injured groups relative to the nonhead-injury trauma group. Linear regression analysis of all 75 trauma subjects demonstrated that three metrics for horizontal disconjugacy negatively correlated with SCAT3 symptom severity score and positively correlated with total Standardized

Assessment of Concussion score. Only 39 (11 of 23 nonhead-injured cohort, 22 of 39 negative head CT cohort, and 6 of 13 positive head CT cohort) of the 75 trauma participants returned at least once for follow-up evaluation. Though there were no differences in symptom severity among the participants who returned for follow-up versus those who did not in the CT- or CT+ groups, among the nonhead-injured controls, those with more symptoms on SAC assessment were more likely to complete follow-up (Mann-Whitney's test, p=0.005). Abnormal eye-tracking metrics improved over time toward baseline in brain-injured subjects observed during follow-up. The authors concluded that the eye tracking device correlates with extent of symptoms assessed with SCAT3, and may quantitate physiological impact of brain injury regardless of whether it is evident on CT scan.

While the authors concluded that eye tracking without spatial calibration may help quantify the severity of ocular motility disruption associated with concussion and structural brain injury, they also acknowledged some study limitations. For example, in the control cohort, the authors relied on self-report for ophthalmic and medical history. Many participants were hospital employees, research volunteers, colleagues, or friends of the investigative team and may not have been completely forthcoming about their past medical history, medications, and drugs used in the day preceding eye-tracking testing. The long-term impact of medications and other substances consumed more than 1 day prior to testing is unknown. Additionally, not all of the study participants in all comparison groups were on the same concomitantly administered medications. As an example, the medication Keppra occurred more commonly in one group than the others and may have contributed to abnormal eye movements in the positive head CT group. However, the negative head CT cohort had similar eye movement abnormalities as the positive head CT cohort and none of these participants had consumed Keppra. The authors also acknowledged that strabismus, some congenital conditions, and some conditions leading to acquired disconjugacy might yield a false positive with the algorithm. Lastly, the authors indicate that because neither formal optometric nor ophthalmic testing was performed in the trauma setting, it could be useful to conduct additional studies that compared eye movement assessments conducted by trained neurological or ophthalmic consultants to those conducted by the eye-tracking device.

A review of the ClinicalTrials.gov database indicates that Dr. Uzma Samadani was the principal investigator of a clinical trial entitled "Use of Eye Movement Tracking to Detect Oculomotor Abnormality in Traumatic Brain Injury Patients" that was completed in June 2018 (ClinicalTrials.gov, 2018). However, at the time of this review, the results of this clinical trial have not been published.

Although preliminary research exploring the use of eye movement analysis using non-spatial calibration to diagnose concussion appears promising, at this time there are very few published clinical studies, and the clinical utility of this technology is unproven. While there are some studies that suggest oculomotor dysfunction is present in some individuals with brain injury, there is a lack of peer-reviewed studies demonstrating that eye movement analysis using non-spatial calibration can be used to accurately and reliably diagnose concussion. Further well-designed studies on non-spatial eye movement analysis are needed to draw conclusions about the clinical utility of this technology.

Background/Overview

According to the Centers for Disease Control and Prevention (CDC):

> **A TBI is caused by a bump, blow, or jolt to the head that disrupts the normal function of the brain. Not all blows or jolts to the head result in a TBI. The severity of a TBI may range from "mild" (i.e., a brief change in mental status or consciousness) to "severe" (i.e., an extended period of unconsciousness or memory loss after the injury). Most TBIs that occur each year are mild, commonly called concussions" (CDC, 2019).**

In 2014, approximately 2.87 million TBI-related emergency room visits, hospitalizations, and deaths occurred in the United States. TBI contributed to the deaths of more than 56,800 individuals, including 2529 deaths among children. It has been estimated 812,000 children (17 years of age or younger) were treated in U.S. emergency rooms for concussion or TBI, alone or in combination with other injuries (CDC, 2019).

Concussion may affect multiple clinical domains: cognitive, physical, and emotional or behavioral. Whereas headache is the most commonly reported postconcussion symptom, dizziness, balance disturbances, and confusion or disorientation are also frequently reported. Although amnesia and loss of consciousness were once considered the hallmarks of concussion, neither is required for diagnosis (Scorza, 2019).

Because there is no standard definition or single diagnostic test that can be used to diagnose concussion, healthcare practitioners must rely on clinical guidelines, imaging studies, assessment tools in conjunction with clinical judgment to make a diagnosis of concussion.

The EyeBOX is being investigated as a tool that can assist in the diagnosis of concussion.

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Definitions

Concussion: Injury to the brain resulting from a mild blow to the head, either with or without loss of consciousness.
Also referred to as a mild traumatic brain injury (mTBI).

Convergence: The ability to turn the two eyes inward toward each other in order to view a close object.

Disconjugate eye movement (gaze). A failure of the eyes to simultaneously turn in the same direction.

Glasgow Coma Scale (GCS): A scoring system to describe the level of consciousness in an individual following a traumatic brain injury. It is used to assist with measuring the severity of an acute brain injury.

Vergence: The simultaneous movement of both eyes in opposite directions to obtain or maintain single binocular vision during focusing.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
0615T	**Eye-movement analysis without spatial calibration, with interpretation and report**

ICD-10 Diagnosis	
	All diagnoses

References

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Peer Reviewed Publications:

1. **Armstrong RA. Visual problems associated with traumatic brain injury. Clin Exp Optom. 2018; 101(6):716-726.**
2. **Bin Zahid A, Hubbard ME, Lockyer J, et al. Eye tracking as a biomarker for concussion in children. Clin J Sport Med. 2020; 30(5):433-443.**
3. **Cifu DX, Wares JR, Hoke KW. Differential eye movements in mild traumatic brain injury versus normal controls. J Head Trauma Rehabil. 2015; 30(1):21-28.**
4. **Hawryluk GW, Manley GT. Classification of traumatic brain injury: past, present, and future. Handb Clin Neurol. 2015; 127:15-21.**
5. **Howell DR, Brilliant AN, Storey EP, et al. Objective eye tracking deficits following concussion for youth seen in a sports medicine setting. J Child Neurol. 2018; 33(12):794-800.**
6. **Maas AI, Menon DK, Steyerberg EW, et al A; CENTER-TBI Participants and Investigators. Collaborative European NeuroTrauma Effectiveness Research in Traumatic Brain Injury (CENTER-TBI): a prospective longitudinal observational study. Neurosurgery. 2015; 76(1):67-80.**
7. **Oldham JR, Meehan WP 3rd, Howell DR. Impaired eye tracking is associated with symptom severity but not dynamic postural control in adolescents following concussion. J Sport Health Sci. 2021; 10(2):138-144.**
8. **Samadani U. A new tool for monitoring brain function: eye tracking goes beyond assessing attention to measuring central nervous system physiology. Neural Regen Res. 2015(a); 10(8):1231-1233.**
9. **Samadani U, Farooq S, Ritlop R, et al. Detection of third and sixth cranial nerve palsies with a novel method for eye tracking while watching a short film clip. J Neurosurg. 2015(b); 122(3):707-720.**
10. **Samadani U, Ritlop R, Reyes M, N et al. Eye tracking detects disconjugate eye movements associated with structural traumatic brain injury and concussion. J Neurotrauma. 2015(c); 32(8):548-56.**
11. **Stuart S, Parrington L, Martini D, et al. The measurement of eye movements in mild traumatic brain injury: A structured review of an emerging area. Front Sports Act Living. 2020; 2:5. eCollection 2020. Available at: https://pubmed.ncbi.nlm.nih.gov/33345000/. Accessed on March 29, 2021.**
12. **Thiagarajan P, Ciuffreda KJ, Ludlam DP. Vergence dysfunction in mild traumatic brain injury (mTBI): a review. Ophthalmic Physiol Opt. 2011; 31(5):456-468.**

Government Agency, Medical Society, and Other Authoritative Publications:

1. **Centers for Disease Control and Prevention (2019). Surveillance report of traumatic brain injury-related emergency department visits, hospitalizations, and deaths—United States, 2014. Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Available at:**

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https://www.cdc.gov/traumaticbraininjury/pdf/TBI-Surveillance-Report-FINAL_508.pdf. Accessed on March 29, 2021.
2. Scorza KA, Cole W. Current concepts in concussion: Initial evaluation and management. Am Fam Physician. 2019;99(7):426-434.
3. U. S. Food and Drug Administration (FDA) Decision summary for EyeBOX (DEN170091). Brain Injury adjunctive interpretive occulomotor assessment aid. Rockville, MD: FDA. December 28, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170091.pdf. Accessed on March 29, 2021.

Websites for Additional Information

1. Centers for Disease Control and Prevention (CDC). Traumatic Brain Injury & Concussion. TBI: Get the Facts (2019). Available at: https://www.cdc.gov/traumaticbraininjury/get_the_facts.html. Accessed on March 29, 2021.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.