Immediate Post-Concussion Assessment and Cognitive Testing (ImPACT)

Assesses concussions by providing pre and post head injury evaluations; also informs return-to-play readiness.

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WHAT IT DOES

ImPACT (Immediate Post-Concussion Assessment and Cognitive Testing) is a new industry offering, promoted as “the only FDA-cleared concussion assessment aid for ages 5-59.” The tool is a computerized concussion management program, designed to provide a guideline for concussion evaluation, ultimately enabling a licensed healthcare provider to diagnose a concussion, inform treatment, and consider if/when an athlete may return to play. The ImPACT test format consists of baseline and post-injury assessments, available for children ages 5-11 years, as well as those aged 12-59 years:

1) Baseline test - Before a sports season starts, each student or professional athlete takes a baseline test, to establish how one’s brain functions in normal, everyday circumstances. This assessment takes approximately 25 minutes to complete and is then stored in the company’s data server, which is compliant with the U.S. Health Insurance Portability and Accountability Act (HIPAA), Canada’s Personal Information Protection and Electronic Documents Act (PIPEDA), and the EU’s General Data Protection Regulation (GDPR).

2) Post-injury test - In the event an individual sustains a head injury and is at-risk for concussion, this person takes a post-injury test; the results are compared to the baseline scores and/or normative data scores by a licensed health care provider who will determine whether the individual has sustained a concussion and if/when the injured person may return-to-play. If an athlete scores substantially lower on the post-injury test than the baseline score, the athlete will not be allowed to return-to-play until the post-injury test scores return to the level of one’s baseline.

This program evaluates multiple aspects of neuropsychological function, including: health history; inventory of concussion-related symptoms such as headache and mental fogginess; attention span; motor processing speed; reaction time; working memory; non-verbal problem solving; and impulse control.

Since 2006, over 7.5 million individuals around the world have taken the ImPACT test. According to ImPACT, the tool is currently used by 7,400 high schools and 1,000 colleges and universities to help evaluate and manage suspected concussions. Schools and teams subscribe on an annual basis; package prices are set according to varying test quantities (e.g., 135 baselines and 15 post-injury tests cost $435 per year). Healthcare providers purchase tests on an individual basis ($12 per baseline; $24 per post-injury). For an additional fee, company neuropsychologists offer test interpretation. The ImPACT Passport Mobile App also allows parents and test takers to store baseline test results, which can be provided to Passport trained healthcare providers for purposes of post injury comparative evaluation.

RELEVANT SCIENCE

The brain is a soft organ that is surrounded by a clear fluid called cerebrospinal fluid (CSF) and protective membranes, called meninges. Normally, the fluid around the brain functions like a cushion that keeps the brain from banging into the skull. A blow to the head or body, a fall, or another injury that jars or shakes the head and body, can cause your brain to be pushed against the skull, thereby bruising the brain and tearing nerve tissues, ultimately resulting in a concussion. This condition is a form of mild Traumatic Brain Injury (TBI), which can cause a temporary disturbance in brain function. Since the brain is a complex organ that
processes sensory information and ultimately controls our senses and movements, giving us the ability to feel and think, a brain injury can cause a broad range of impairments in physiological and psychological functions.

Effects of a concussion are usually temporary, but in rare instances can last over a year. Symptoms of a concussion can be categorized into four groups, which manifest in the following ways:

● Thinking and remembering
  ○ Not thinking clearly
  ○ Feeling slowed down
  ○ Not being able to concentrate
  ○ Not being able to remember new information
  ○ Inability to remember what happened immediately before or after the injury (amnesia)
  ○ Loss of consciousness

● Physical
  ○ Nausea and vomiting
  ○ Headache
  ○ Fuzzy or blurry vision
  ○ Dizziness
  ○ Sensitivity to light or noise
  ○ Balance problems
  ○ Feeling tired or having no energy
  ○ Ringing in the ears (tinnitus)

● Emotional and mood
  ○ Easily upset or angered
  ○ Sad
  ○ Nervous or anxious
  ○ More emotional

● Sleep
  ○ Sleeping more than usual
  ○ Sleeping less than usual
  ○ Having a hard time falling asleep

Any person who suspects they may have a concussion needs to see a healthcare provider for official diagnosis. If a clinician thinks that you have a concussion, they will ask questions about the injury and may also test your attention, learning ability, and memory. They may also check your strength, balance, coordination, reflexes, and sensation.

A healthcare practitioner may also use neuropsychological tests to assess whether a concussion impacts your physical and psychological functioning, usually determined through the use of questionnaires. Sometimes a doctor may order brain imaging tests such as a Computed Tomography (CT) scan or Magnetic Resonance Imaging (MRI), to assess whether the brain is bruised or bleeding.

In 2012, an estimated 329,290 children (age 19 or younger) were treated in U.S. emergency rooms for sports and recreation-related injuries that included a diagnosis of concussion or TBI.

It’s particularly important that athletes don’t return to play until they are fully recovered, since doing so too soon can increase an athlete's chances of developing a persistent head injury called Second Impact Syndrome (SIS), “a condition so rare that even the frequency of its occurrence is in question.” SIS is a situation in which a second head injury occurs before a first concussion has properly healed, causing rapid and severe brain swelling and brain herniation. SIS can occur with any two events involving head trauma. Most cases of SIS have occurred in young athletes, particularly those who participate in sports such as boxing, baseball, football, hockey, and skiing. It can occur in the same game or competition if the athlete isn’t removed and treated after the first concussion. Symptoms usually occur immediately following the second impact and progress rapidly. Common symptoms include:
dilated pupils, loss of eye movement, loss of consciousness, respiratory failure, and death.

WHY IT MATTERS

Public concern regarding sports-related concussions is on the rise; this topic is garnering increased attention from the media, professional sports leagues, as well as law and policy-making bodies. Before the creation of ImPACT, widespread use of a standardized concussion assessment tool was lacking. Historically, those who sustained head injuries have often been responsible for self-reporting a suspected concussion. Return-to-play standards and guidelines have also been variably implemented.

Concussions and traumatic brain injuries have increasingly received national attention. In 2013, former professional football players reached a $765 million settlement against the NFL; they claimed to have memory loss, depression, headaches, and dizziness after suffering from multiple head injuries over the course of their careers. It’s not just athletes; the U.S. Department of Defense estimates that 22 percent of all combat injuries in the Iraq and Afghanistan conflicts are traumatic brain injuries.

RELEVANT EXPERTS

Jeffrey R Bytomski, DO, FAOASM, is a sport medicine specialist and physiatrist at Duke Health. His clinical interests include non-operative musculoskeletal medicine as well as medical issues in athletes, including concussions and post-concussion syndrome. He helps coordinate the Duke Sports Concussion Clinic. He also performs compartment pressure testing for evaluation of chronic exertional compartment syndrome. He is a certified ImPACT consultant for concussions, and offers baseline concussion testing for athletes. Relevant publications include:

- Brog Hess, BR; Bytomski, JR, Medicolegal aspects of sports medicine., Prim Care, 40(2) (2013), pp. 525-535.

Barry Myers, M.D., PhD., MBA., is a professor of Biomedical Engineering and director of research at Duke Clinical & Translational Science Institute (CTSI). His research examines the biomechanics of head and neck injury with the goal of injury prevention. At Duke CTSI, he consults the service that provides funding and project management support to faculty translational research projects in the Duke Medical Center. Dr. Myers also created and leads a national translational research fund intended to reduce injuries in professional football. Relevant publications include:

- Adamski, KN; Loyd, AM; Samost, A; Myers, B; Nightingale, R; Smith, K; 'Dale' Bass, CR, Pediatric Coronal Suture Fiber Alignment and the Effect of Interdigitation on Coronal Suture Mechanical Properties., Annals of Biomedical Engineering, vol 43 no. 9 (2015), pp. 2101-2111.
- Nightingale, RW; Myers, BS; Yoganandan, N, Neck injury biomechanics (2015), pp. 259-308.

BACKGROUND

ImPACT is not the only available concussion assessment tool. Others include:

1. The Sport Concussion Assessment Tool (SCAT) - Evaluates people who are possibly suffering from sports concussions; used in athletes starting at 13 years old. The original SCAT was produced in 2004 as part of the Summary and Agreement Statement of the Second International Symposium on Concussion in Sport (CIS; published in 2005); SCAT2 and SCAT3 were updated in 2009 and
The SCAT3 score does not independently determine the diagnosis of a concussion, nor does it independently determine the injured athlete's recovery or return to play status. Such determination can only be made by a medical professional who has training and experience in treating sport concussions. The SCAT3 measures the following sections: symptom evaluation, cognitive assessment-Standardized Assessment of Concussion (SAC), balance examination, coordination examination. The SCAT 3 has a graded symptom scale going from 0 (indicating no symptoms), 1 (very mild), up to 6 (severe). This tool can also be used for pre-season baseline assessments, to be compared to future post-injury test scores.

2. The Standardized Assessment of Concussion (SAC) - Provides immediate cognitive screening for athletes who may have incurred a concussion. The test contains questions designed to assess athletes’ orientation, immediate memory, concentration, and delayed memory. It also includes an exertion test and brief neurological evaluation. The SAC takes approximately 5 -7 minutes to administer and does not require a neuropsychologist to evaluate test scores. However, because it tests only for verbal memory, the SAC cannot identify athletes who may suffer measurable impairment of neurocognitive function (primarily visual working memory) on neurocognitive tests. The SAC is not meant to replace comprehensive neuropsychological testing or to be used as a stand-alone tool to diagnose concussions, measure recovery, or make decisions about an athlete's readiness to return to competition.

3. Automated Neuropsychological Assessment Metrics (ANAM) - Detects the accuracy and efficiency of cognitive processing through a computer-based neuropsychological assessment tool. ANAM measures attention, concentration, reaction time, memory, processing speed, and decision making. Test results can be used for healthcare professionals to assess cognitive change that may have been caused by injury, fatigue, illness, exposure, or medical intervention.

4. The Glasgow Coma Scale (GCS) - Describes a person’s level of consciousness following a traumatic brain injury (TBI) by using a common scoring system. It is used to help gauge the severity of an acute brain injury, but not cognitive function. The GCS is scored between 3 and 15; 3 being the worst and 15 the best. The GCS measures eye opening, verbal response, and motor response.

5. King-Devick Tests - Measures eye movements, along with the speed and accuracy of naming numbers. These tasks detect impairments of eye movements, attention, language, and other indicators that correlate with suboptimal brain function. The Mayo Clinic endorses this method as an accurate screening test to determine whether an athlete should be sidelined. This test takes approximately two minutes to complete.

ENDORSEMENTS & OPPOSITION

Endorsements:

- **The Center Foundation**, located in Oregon, provides the ImPACT tests for free to Central Oregon athletes in high-risk sports in order to comply with requirements of Max's Law, a state requirement that Oregon school districts implement concussion management plans for athletes.

- **The Nebraska Sports Concussion Network** funded baseline testing for 7th through 12th grade athletes participating in collision and contact sports with the highest incidence of concussions, including football, volleyball, basketball, wrestling, diving, soccer, track-jumpers, baseball, and softball; 75% of all Nebraska high schools are using the tool.

- Some professional sports teams use the tool, including the National Football League (NFL), National Basketball Association (NBA), National Hockey League (NHL), and Major League Baseball (MLB).

- Collegiate level teams are also signing up to use the tool, including numerous National Collegiate Athletic Association (NCAA) Division I football programs. Other athletic programs in Nebraska are currently implementing the program, such as, Doane College, Concordia University, Peru State College, UNO, and UNK.
Opposition:

A number of studies and experts question the validity and reliability of ImPACT testing. These studies suggest that an ImPACT test should not be a superior measure to diagnose lingering concussion symptoms or to judge when an individual is fully recovered. Also, using a multifaceted approach is suggested. Reasons include:

- **Arthur Maerlender** and his colleagues in the Center for Brain, Biology and Behavior at University of Nebraska detected that 65 to 70 percent of subjects intended poor performance on the baseline test. Some athletes have intentionally flubbed their baseline tests to have a lower score in the hope of playing sooner after a concussion. This can ruin the validity of the test and ultimately increase the likelihood of permanent brain damage.

- **Steven Broglio** and his colleagues in the University of Illinois found fluctuating scores even with healthy students, which showed a 40 percent false-positive rate of ImPACT scores.

- **Michael Barlow** and his colleagues at Walsh University showed that reliability of the test is unacceptably low by arguing that interpretation of test scores is difficult. Observation of a drop in the score for reaction time cannot be directly connected to brain impairment because many conditions affect test performance, such as a person's lack of sleep or high level of caffeine consumption. Further, ImPACT administrators may not have been trained professionally in neuropsychological testing or data interpretation. Also, because an adolescent brain is still immature, differences in scores from one test to the next could be attributable to other factors influencing brain development.

**STATUS**

In August, 2016, the U.S. Food and Drug Administration permitted the marketing of ImPACT and ImPACT Pediatric for assessment of cognitive function following a possible concussion. This class II medical device was reviewed via the FDA’s de novo classification pathway, which allows for classification of novel, low- to-moderate-risk medical devices that are first-of-a-kind, but have reasonable assurance of safety and efficacy. FDA codified the classification of the device by adding “Computerized cognitive assessment aid for concussion” as a new category of Neurological Diagnostic Device (21 CFR 882.1471).

**RELATED POLICIES**

**Federal**

The Centers for Disease Control and Prevention’s Heads Up Initiative produced a publication for parents and administrators, stating: “Recently, many states, schools, and sports leagues and organizations have created policies or action plans on concussion in youth and high school sports. While these policy efforts show some promise, more research is needed to learn if these strategies can help educate coaches and parents about this issue and help protect children and teens from concussion and other serious brain injuries.”

**State**

Since 2007, state legislatures in all 50 states and the District of Columbia have enacted legislation to address youth sports-related concussion. The vast majority of these laws share three components:

- Provision of education or training on concussion recognition and appropriate responses.
- Removing a youth athlete from play or practice in the event of a suspected concussion.
- Returning a youth athlete to practice or competition after evaluation and clearance by a designated health care provider.

Examples of bellwether state actions include Washington and Oregon. In 2009, Washington passed legislation to address concussion management in youth athletics, becoming the first state law to require a “removal and clearance for Return to Play” among youth
athletes. Now all 50 states have a Return to Play law. Max’s Law (OAR 581-022-0421) created an Oregon Administrative Rule that required school districts to implement new concussion management guidelines for student athletes. Successful concussion management policies follow a “Recognize, Remove, Refer, Return” protocol. In 2013, another Oregon bill, Jenna’s Law (ORS 417.875), was passed with the aim of providing similar guidelines for coaches and officials in “nonschool athletics,” such as local youth soccer clubs and Little League organizations.

ORGANIZATIONS

ImPACT is manufactured by ImPACT Applications, located in Pittsburgh, Pennsylvania. ImPACT is a research-based software tool developed by neuropsychologist Mark Lovell, the CEO of ImPACT Applications Inc., along with University of Pittsburgh neurosurgeon Joseph Maroon.

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