DETECT: An Integrated Platform for Multimodal Assessment of Brain Function

DETECT™

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The Problem

Concussion recognition difficult

- **Signs & symptoms are variable and subtle**
- **Each concussion is unique**

Missed concussion → athlete vulnerable

The Problem

No single tool will give an accurate picture of injury state

- Symptoms
- Impact data
- Neurocognitive
- Balance
- Vestibulo-ocular

→ **Variable outcomes**

→ **Misdiagnosis**

→ **Under-diagnosis**

The Solution

DETECT (**D**isplay **E**nhanced **Te**sting for **C**ognitive Impairment and m**T**BI)

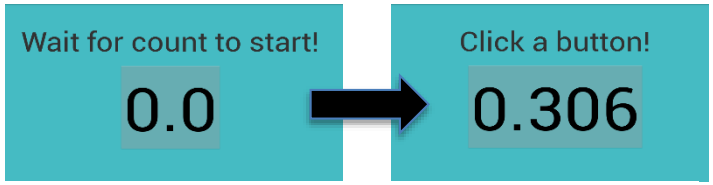
A portable, immersive, comprehensive tool to identify neurologic impairment through administration of multimodal, objective tests

- **Symptom checklists**
- **Neurological symptoms**
- **Neurocognitive testing**
- **Balance testing**
- **Vestibulo-ocular integrity**

Multimodal Concussion Assessment

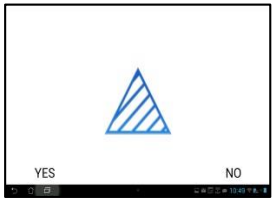
DETECT assessments
✓ Neuropsych
✓ Reaction Time
Nonpostural Balance
Target Tracking

Reaction Time Test



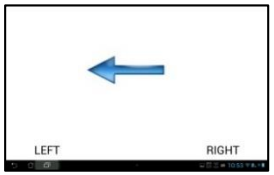
The user must maintain vigilance and wait for the timer to press the button

Neuropsychological Test



SHAPES: Complex Choice Reaction Time processing speed and divided attention ✓✓

WORD RECALL: Selective Reminding Working Memory (learning and recall) ✓



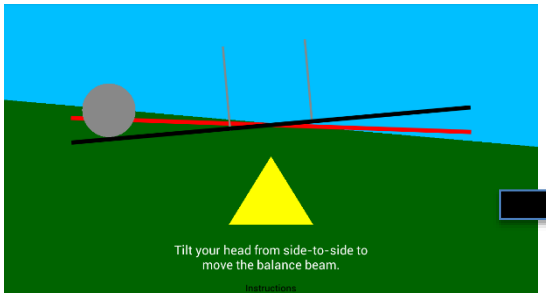
ARROWS: Conditional Choice Reaction Time processing speed and divided attention ✓

Espinoza et al, *Neurotrauma Reports* (2021)

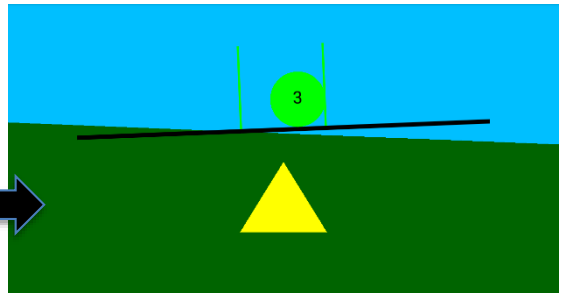
Multimodal Concussion Assessment

DETECT Assessments
Neuropsych
Reaction Time
✓ Nonpostural Balance
✓ Target Tracking

Non-Postural Balance Test



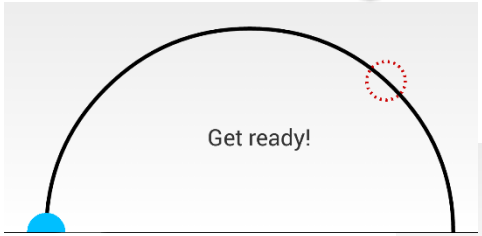
The user is instructed to tilt their head from side to side to balance the ball on the beam



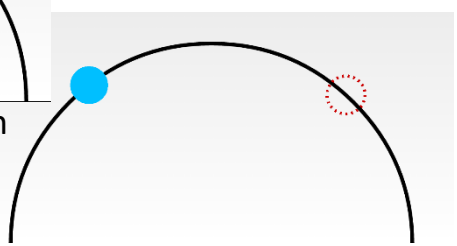
As the user places the ball in the target area, a 3 second countdown is initiated, during which the ball must remain in the target area

Target Tracking Test

Oculomotor function



Starting position for each target tracking trial



The user must track the ball to the target and press the button

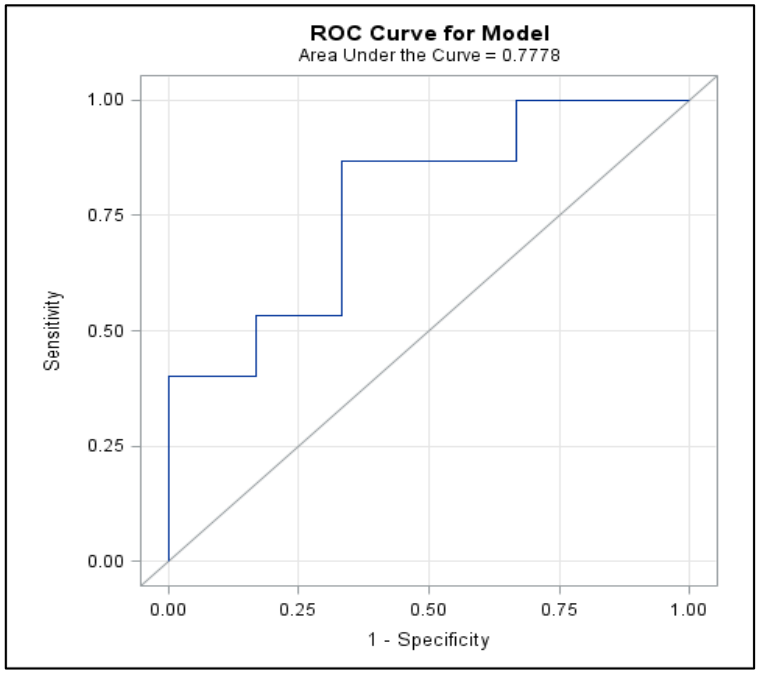
NPT Results Concussion Study

- Identification of concussions (n=15) among all suspected concussions (n=21):

  Sensitivity: 86.7%
  (95% CI: 59.5%, 98.3%)
  Specificity: 66.7%
  (95% CI: 22.3%, 95.7%)

- Identification of concussions among all players with (n=21) and without (n=64) suspected concussion:

  Sensitivity: 86.7%
  (95% CI: 59.5%, 98.3%)
  Specificity: 47.1%
  (95% CI: 35.1%, 59.4%)



Discrimination of DETECT score for final diagnosis of concussion among players with suspected concussion (n=21)

DETECT confers very good sensitivity in identifying cognitive impairment in the minutes following a concussion

Several NPT subtests within DETECT show promise for identifying concussion in the absence of baseline testing

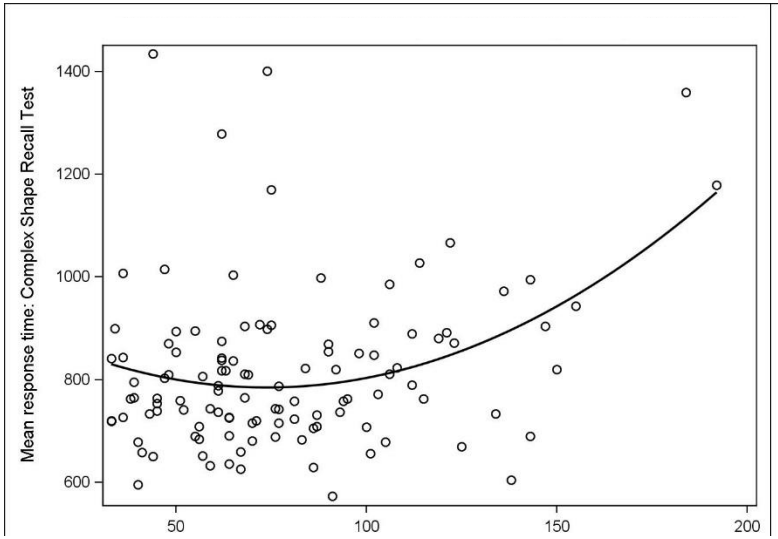
Subconcussive Cognitive Deficits

DETECT™

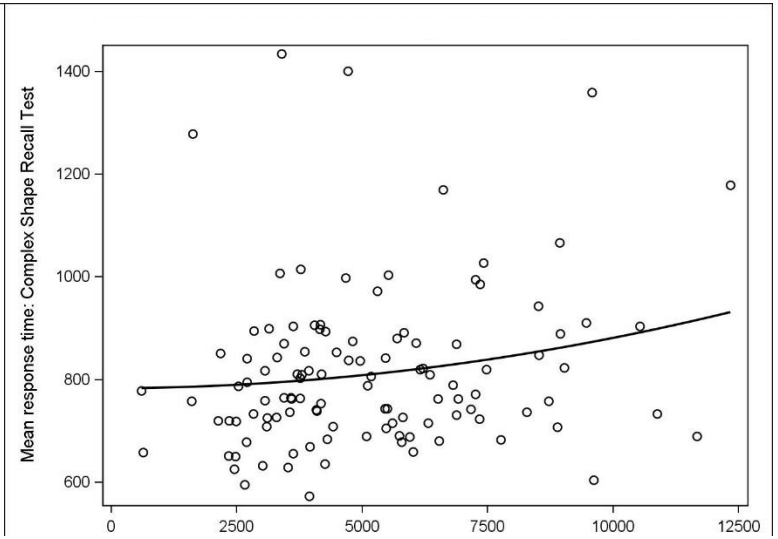
Complex Choice Reaction Time test

- n=113 tests on 77 players
- Mean reaction time significantly increases with increase in linear (Spearman's coefficient 0.262; p=0.02) AND rotational (Spearman's coefficient 0.254 , p=0.03) acceleration

Linear

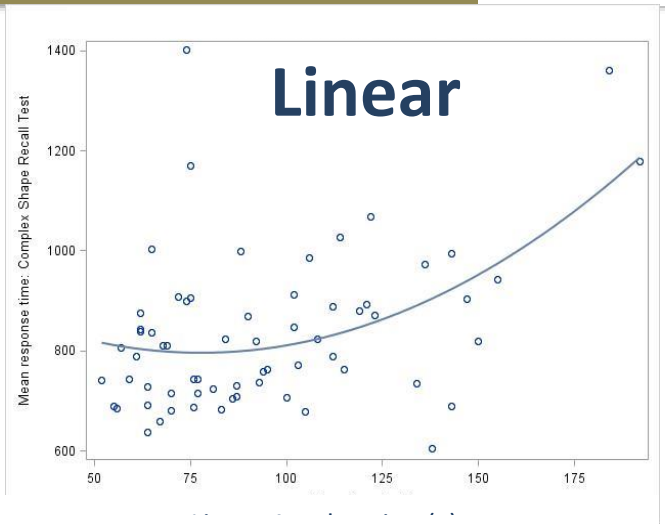


Rotational

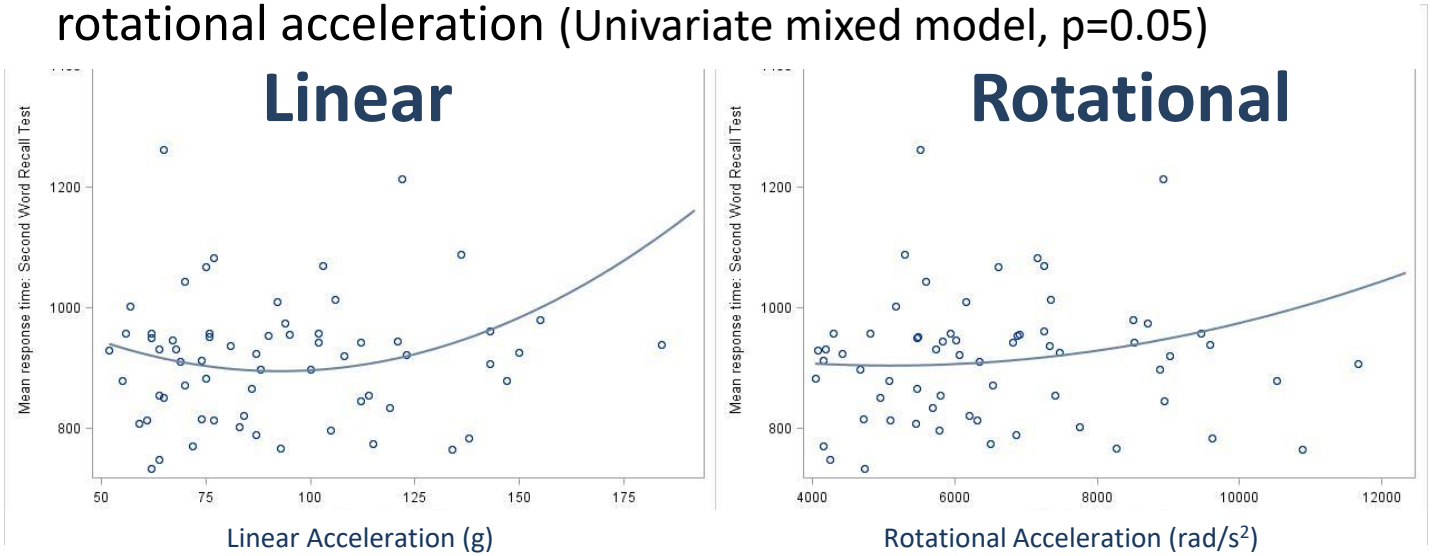


Subset Analysis: Highest level impacts

- Linear acceleration >50 g & rotational acceleration >4000 rad/s^2, n=56
- **Complex Choice Reaction Time** correlates with linear acceleration (Spearman coefficient 0.267, p=0.05; Univariate mixed model, p=0.03)



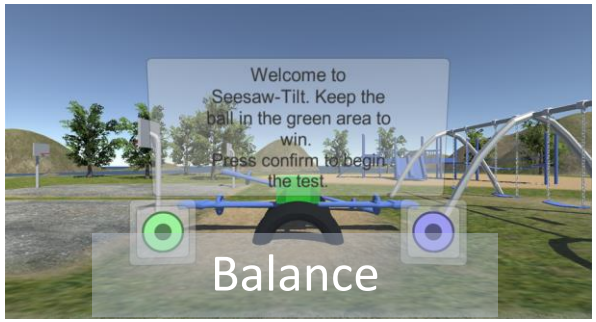
- **Selective Reminding** response time correlates with linear and rotational acceleration (Univariate mixed model, p=0.05)

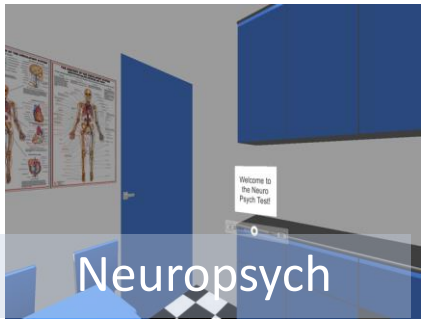


Current Generation DETECT

3D-VR DETECT System
‘Gamification’ Virtual Reality Environment

*next generation: integrated VR





System Features

- Software application for smart phones
- Virtual Reality (VR) headset
- Patient information entered prior to assessment
- Trained medical personnel administer
- Data uploaded to HIPAA compliant database
- Objective output for subtest modalities and overall score
- Intended to aid in clinical decisions and management

Samsung Gear VR Headset	Samsung Gear VR Headset plus Galaxy Phone	Samsung Gear VR Headset plus Galaxy Phone Being Used
		

Kids and Concussion

Pediatric DETECT (PeDETECT): Multimodal Concussion Assessment in Children using Virtual Reality

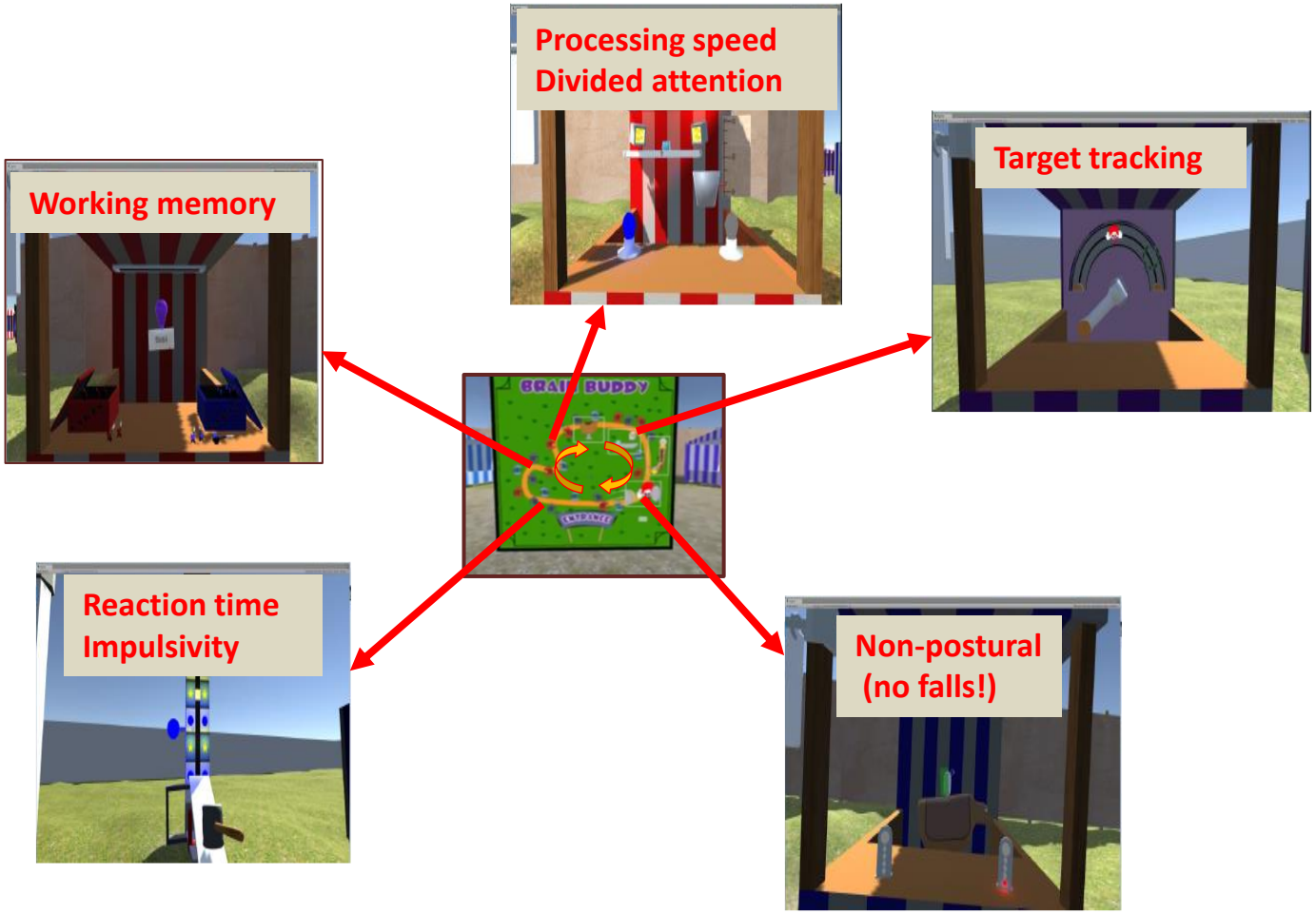
Emergency Department treatment of concussion for 19 yo and younger, from 2001 to 2009 in US:

- **Increased from 150,000 to 250,000**
- **Up 57% (from 190 to 298 per 100,000)**

PeDETECT Device

- ***Pediatric-oriented game-like VR tests***
  - **Neuropsychological assessment**
    - Working memory
    - Processing speed
    - Divided attention
    - Reaction time
  - **Balance Assessment**
    - Non postural balance
  - **Oculomotor Assessment**
    - Target tracking

PeDETECT Tests



Intellectual Property Portfolio

Patent Application No.	Filing Date	Title	Owner/ Licensee	Status
U.S. Patent. No. 11/503,579	2006	DISPLAY ENHANCED TESTING FOR CONCUSSIONS AND MILD TRAUMATIC BRAIN INJURY	Emory / Georgia Tech	Issued as U.S. Patent No. 8,568,311 on 10/29/2013
U.S. Prov. Patent No. 62/049,541	2014	METHODS AND SYSTEMS FOR DETERMING BALANCE BASED ON NON-POSTURAL INFORMATION	Emory / Georgia Tech	Provisional filed 9, 2012 – Full to file in 9-2015

IP resides jointly with Emory University and Georgia Institute of Technology

Market Competition

Company / Product	Cognitive	Balance	Vision	Symptoms	Sideline	Baseline	Objective	Immersive	Rapid
DETECT	✓	✓	✓	✓	✓	✓	✓	✓	✓
ImPACT	✓	✗	✗	✓	✗	✓	✓	✗	✗
Cogstate/ Axon Sports / CCAT	✓	✗	✗	✓	✗	✓	✓	✗	✗
CNS Vital Signs	✓	✗	✗	✓	✗	✓	✓	✗	✗
BESS	✗	✗	✗	✗	✓	✓	✗	✗	✗
Sway	✗	✗	✗	✗	✗	✓	✓	✗	✗
King-Devick	✗	✗	✓	✗	✓	✓	✓	✗	✓
SCAT3	✓	✓	✗	✓	✓	✓	✗	✗	✗
C3Logix	✓	✓	✓	✓	✓	✓	✗	✗	✗

Market Advantage

1. DETECT is *immersive*

A VR environment will be natural and engaging

2. DETECT is *multimodal*

Testing multiple domains of concussion is recommended

3. DETECT output driven by *informatics driven data analysis*

Clinical decision tools should consider multiple factors

Smart algorithms can adapt and account for developmental factors

Value Proposition

Save Medical Costs

- Reduces risk of recurrent injury and concussion complications
- Mitigates risk (injury and medicolegal)

Save Overall Program Costs

- Streamline Assessment
- Complete solution (bundled tests in one platform)

Improve Quality

- Allows compliance with developing rules and standards
- Offers marketing & recruiting opportunities

Make collision sports safer - protect the athlete and the game!

Regulatory

- **FDA Considerations**
  - 501(k), Class 2, POM
  - Indication: Concussion
  - Intended use: Aid to assessment and management of concussion
  - Pre-submission Fall 2018

- **Measures Neurological Function**
  - *Change* from normal, ***not diagnostic*** for concussion
  - *Comparison* to ***normal population***

Stakeholders: Problems & Needs

<u>Customers/Users:</u> Athletic Trainers, Team Assistants, Sports MDs,

- Using multiple tools is impractical
- Not enough expertise at high school level
- Lack of objective, rapid, reliable tools

<u>Customers/Finance</u>: Athletic Directors, School Administrators

- Desire to minimize risk of injury
- Changing standards & compliance environment
- Uncertainty regarding best way to protect athletes

Funding & Partnerships

***Funding*: DoD-CDMRP/USAMRMC, Coulter Foundation, NFL / GE / UnderArmour Head Health Challenge II**

Clinical Partners:

Industry Partners:

Academic Partners:

Sports Teams: