Concussion Management Systems

I/UCRC BWAC PLANNING GRANT WORKSHOP
UNIVERSITY OF MISSISSIPPI Jan 15, 2015
X2 merges advanced electronic sensors, wearable biometric devices, **wireless communications**, and cloud data analytics to:

- Monitor head impacts and enable fast, accurate identification of potential concussions
- Support comprehensive, personalized concussion care and return-to-play for athletes, civilians, industrial, and military personnel.
xPatch ranked one of the 25 most exciting medical MEMS and sensors devices - 2014

http://www.slideshare.net/MikePinelisPhD/140804-25-most-interesting-medical-mems-sensors
Research & Development Challenges

• Real time recording, processing, and wireless transmission of high precision impact sensor data (to sidelines & cloud) to help identify location & severity of compressive, tensile, and rotational shear stress

• **Wireless mesh networking of sensors**, combining data from multiple impact participants to identify and discard spurious triggers, correlate multiple impacts

  - ZigBee, ANT, WiFi, Bluetooth, BLE, WiSUN,… (tradeoffs in power consumption, $T_X$ range vs. power, $R_X$ sensitivity, data rate, start-up time, delay, latency, capacity, cost, market readiness…)

• Energy harvesting for extended battery life or **self-powered wireless devices**

• Enhancing impact classification **algorithms (data mining, machine learning, …)** leveraging **activity-specific and athlete-specific biometric information**, 

• Extending X2 data analysis and software apps to deliver finite element **visualizations of potential tissue & structural connectome damage** arising from measured head impacts
Thank You!

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Concussion Figures in the US

$76.5B
Estimated cost of Traumatic Brain Injury (TBI) in the US in 2010, including direct medical costs and loss of productivity.

75%
Percentage of TBIs characterized as concussions (or “MTBI” - Mild Traumatic Brain Injury) resulting from head impacts (direct or indirect) in sports, military service, and other civilian and industrial activities.

3,800,000
Sports-related concussions diagnosed each year in the US. As many as 40-60% more may remain undiagnosed, and combined military, civilian, and industrial figures are estimated to be even higher.

50
Number of US states that have introduced “Lystedt” youth concussion laws as of July 2014, requiring immediate removal from play if concussion is suspected, and medical clearance to return to play.

Concussion-related Disabilities

Concussions are now known to lead to wide range of short-term and long-term disabilities, including:

- Cognitive functions (e.g., attention and memory)
- Motor functions (e.g., impaired coordination and balance)
- Sensory functions (e.g., vision, speech, hearing)
- Emotion and Behavior (e.g., depression, anxiety, aggression, impulse control, personality changes)

*Source: US Centers for Disease Control and Prevention*
### Leadership Team

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<tr>
<th>Name</th>
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| John Ralston, PhD     | Chairman & CEO                             | 25+ years spanning R&D, marketing, sales, CEO
|                        |                                            | system-on-chip technologies, wireless & wearable devices, mobile apps, SaaS platforms, big data/analytics for medical and smart grid industries. |
| Rich Able             | Co-Founder VP Business Development          | 20+ years of medical device sales & marketing
|                        |                                            | Abbott Laboratories, Roche Diagnostics, McKesson HIS, Stratos Product Development
|                        |                                            | Former US Army Artillery Officer                                                                                   |
| Roberto Linares       | VP Finance & Operations                     | Extensive startup finance, operations experience
|                        |                                            | 12 years corporate finance, investment banking, accounting with Barclays, Citibank, Deutsche Bank
|                        |                                            | Defender, soccer                                                                                                   |
| Major General (Ret)   | VP Government & Industrial                  | 30 years experience managing large diverse American and multi-national organizations
| Steve Layfield        |                                            | Director, Joint Warfighting Center, J7
|                        |                                            | Deputy Commander, NATO Afghanistan mission                                                                         |
| Ed Mlinek, MD         | Head of Clinical Affairs                    | 27 years experience in Emergency Medicine
|                        |                                            | Medical Officer, Urban Search and Rescue, Department of Homeland Security                                           |
|                        |                                            | Medical Director, U.S. Special Olympics, 2010                                                                      |
| Phil Heywood, ATC     | Head of Athletic Training                   | Director of Athletic Training, Seattle Children’s Hospital
|                        |                                            | Program Manager, Seattle Sports Concussion Program                                                                 |

We are driven by a fierce passion developed over years of playing alongside, coaching, training, leading, and caring for athletes, military, civilian, and industrial personnel who have been and continue to be exposed to concussion risk - many of whom continue to suffer from a wide range of short-term and long-term disabilities that are now known to arise from head impacts.
Complete Continuum of Care sets X2 apart from other solutions:

- Wearable sensors for real-time impact monitoring, multiple form factors to support multiple sports
- HIPAA-compliant cloud-based storage and processing of biometric information
- SW apps enabling collaboration between physicians, players, trainers, coaches, neuropsychologists, parents
  - Concussion Education & Training
  - Baseline Assessment
  - Remove-from-Play Decision Support
  - Recovery and Return-to-Play Management
  - Follow-up Assessments
X2 Technology Overview - Hardware

- **X-Patch wearable impact sensor patch**
- **X-Guard impact sensor mouth guard**
- **X2 “Nose Black” wearable impact sensor prototype**
- **X2 impact sensor engine**
- **X-Band impact sensor headband prototype**

- **Microprocessor and Memory**

- **Tri-Axis Accelerometer**
  - Translational Acceleration
  - Time

- **Tri-Axis Gyroscope**
  - Rotational Velocity
  - Time

- **Impact classification algorithms**
- **Record 6DOF impact kinematics**
- **Identify/discard spurious triggers**
Expanding USA & Global Deployments

More collaborations generating more data from more sports and other activities in more countries than any competitor!

National Coverage:

Current International Footprint
- Canada
- England
- Ireland
- Australia
- New Zealand
- South Korea
Unmatched level of on-field athletic & military testing of X2 mouth guard and skin patch designs

**Validation Highlights: On-Field**

**Men:**
- Football (youth, high school, collegiate, NFL)
- Hockey (NHL)
- Soccer (MLS)
- Lacrosse
- Rugby (amateur, UK professional)
- Boxing
- Taekwondo
- Mixed Martial Arts
- Skiing
- Army Paratroopers

**Women:**
- Soccer
- Lacrosse
- Field Hockey
- Skiing
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Saracens test head safety device

SARACENS rugby players wore a hi-tech device new to the sport for their game against London Irish at Allianz Park yesterday. As part of growing global concern about concussion and other brain injuries suffered in contact sports, their players wore the xPatch, fixed in place below the ear, which contains an accelerometer and a gyroscope to measure the magnitude and angle of hits to the head.

Saracens have worked with the Seattle-based company X2 Biosystems, who provide their concussion management platform to National Football League (NFL) and National Hockey League (NHL) teams in the US. The patches will be now worn in weekly games by the Saracens players and in every training session. After games or training sessions the xPatch is removed and impact data is uploaded onto a tablet or laptop computer. The number, angle and severity of hits are shown for every player.

Each player will have a baseline health assessment before each season. Then, at intervals or whenever a player is perceived via the xPatch to have taken punishment, they undergo cognitive therapy to assess their memory, attention span and concentration. When this is measured against the baseline, the incidence or severity of concussion can be assessed.
Validation Highlights: Clinical, Lab

Unmatched breadth and depth of third party clinical and test lab studies

League-Sponsored Lab Testing

Impact and Blast Chamber Testing with Human Models, Human Cadavers, Animals

Principal strain at time of peak

Location of peak principal strain

Injuries

Departments of Mechanical Engineering, Bioengineering, Medicine, Neurology, Neurosurgery

Department of Neuronic Engineering, Royal Institute of Technology, Stockholm, Sweden

Live Athletic Studies
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Testing football helmets - 1912
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