



HEADSAFE

WORLD FIRST SALIVA BIOMARKER STUDY BEGINS AT RANDWICK RUGBY

This month, Headsafe¹ begins a landmark study into Concussion Biomarkers in rugby players.

Biological markers or "biomarkers" are compounds which are released from damaged nerve cells in the brain. When they move from inside the brain outwards into circulation they can be detected in blood, urine, breath and also saliva. They reflect damage to cells and may eventually be diagnostic for concussion and of use in knowing when an injured sportsperson can return to play safely.

A number of these biomarkers are released following injury and are being studied extensively world-wide². There is also the possibility that some of them are themselves the compounds which actually cause damage to brain cells in concussion. This opens the potential for specific treatments which counter these biomarkers and therefore prevent or treat short, medium and long-term damage.

One of the best publicised biomarkers is Tau Protein, the subject of the Hollywood blockbuster "Concussion", starring Will Smith as acclaimed researcher Dr. Benet Omalu, credited with discovering the Tau biomarker in the brains of deceased NFL footballers. He proposed this as the cause of the condition Chronic Traumatic Encephalopathy (CTE), which is at the centre of a \$1 billion class action settlement between the NFL and a group of past players³.

Dr. Adrian Cohen and his research team will collect small (2ml) samples of saliva before and after matches in the Shute Shield Rugby Premiership from Randwick Rugby Club players over the next three months. The samples will be stored in liquid nitrogen at -70 degrees centigrade and then shipped in a "Cryoport" to maintain these low temperatures whilst in transit to research labs in Boston, USA.

"This is world-class, first-of-its-kind research being conducted right here in Randwick" says Cohen.

These samples will be analysed to detect changes in biomarkers in players who sustain head impacts. These are measured by the XPatch Biosensors⁴ which Headsafe researchers pioneered in Australian rugby in 2015 under a program sanctioned by the Australian Rugby Union and World Rugby. Players will also be assessed using the King Devick Test by Mayo Clinic⁵, a rapid concussion assessment tool utilised widely in sports and a new Smartphone Balance App, in addition to the Sports Concussion Assessment Tool (SCAT3⁶).

According to Cohen

"This study hopes to be able to determine which saliva biomarkers are predictive of acute concussion. We can then monitor the return of these biomarkers to normal levels as an objective test that the player has recovered. No more guesswork.....just good science."

Further information:

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¹ **Headsafe** is the concussion initiative of Necksafe Ltd, dedicated to the elimination of preventable head and neck injuries through advocacy, awareness, education and research and is recognised by the Australian Charities and Not For Profits Commission (ACNC) as a Health Promotion Charity (HPC) with Deductible Gift Recipient (DGR) status

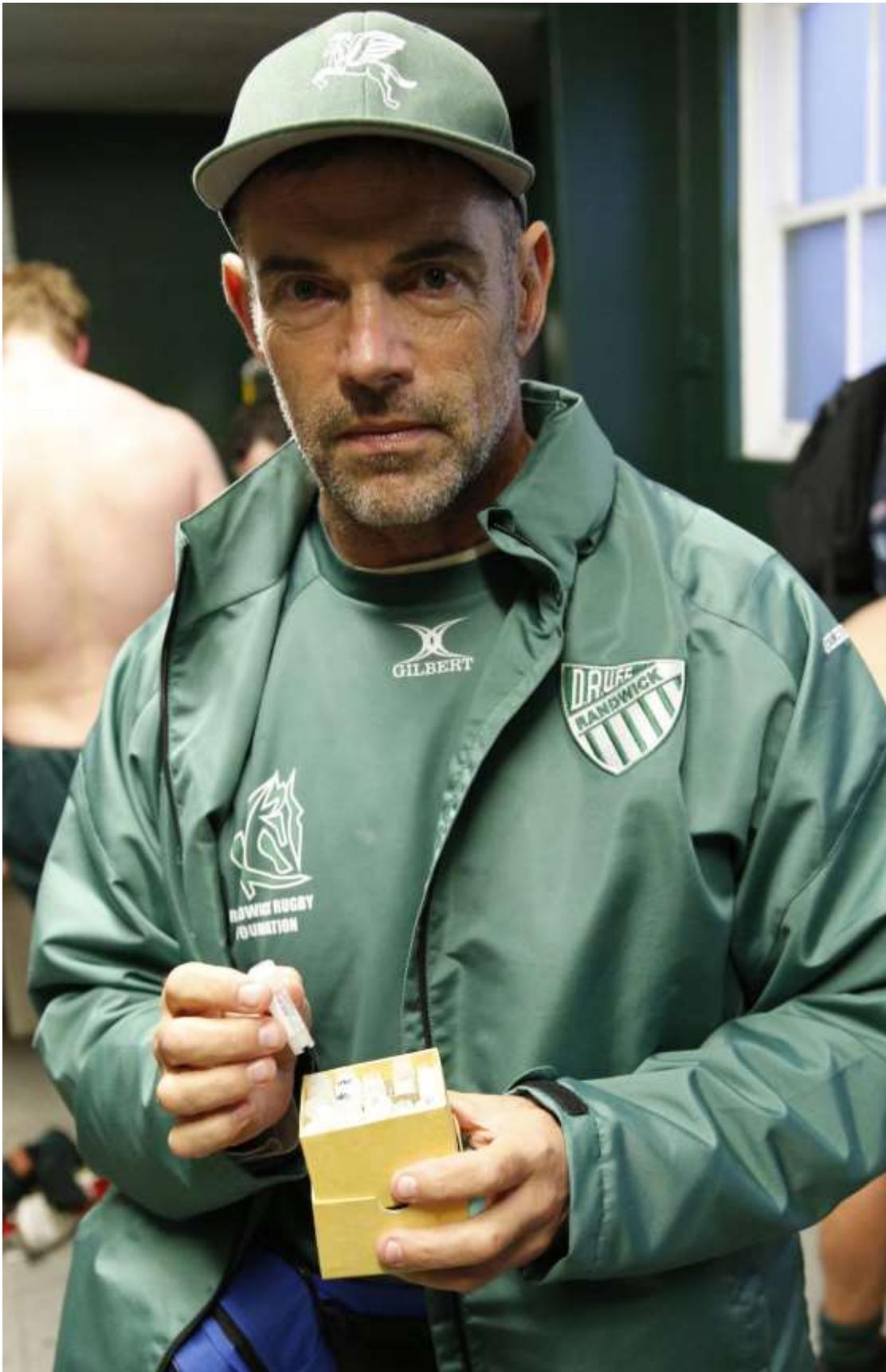
² Some of the biomarkers currently under study include Copeptin; Galectin 3 (LGALS3); Matrix Metalloproteinase 9 (MMP9); Occludin (OCLN), S-100 calcium-binding protein B (S100B), Tau, Glial Fibrillary Acidic Protein (GFAP), Neuro Filament Light Chain (LFL), Ubiquitin C-terminal Hydrolase-L1 (UCHL-1), Phosphorylated Neurofilament Heavy Subunit (pNFH), Amyloid and Calpain-Derived All-Spectrin N-terminal Fragment (SNTF)

³ <http://www.reuters.com/article/us-nfl-concussion-idUSKCN0XF1XG>

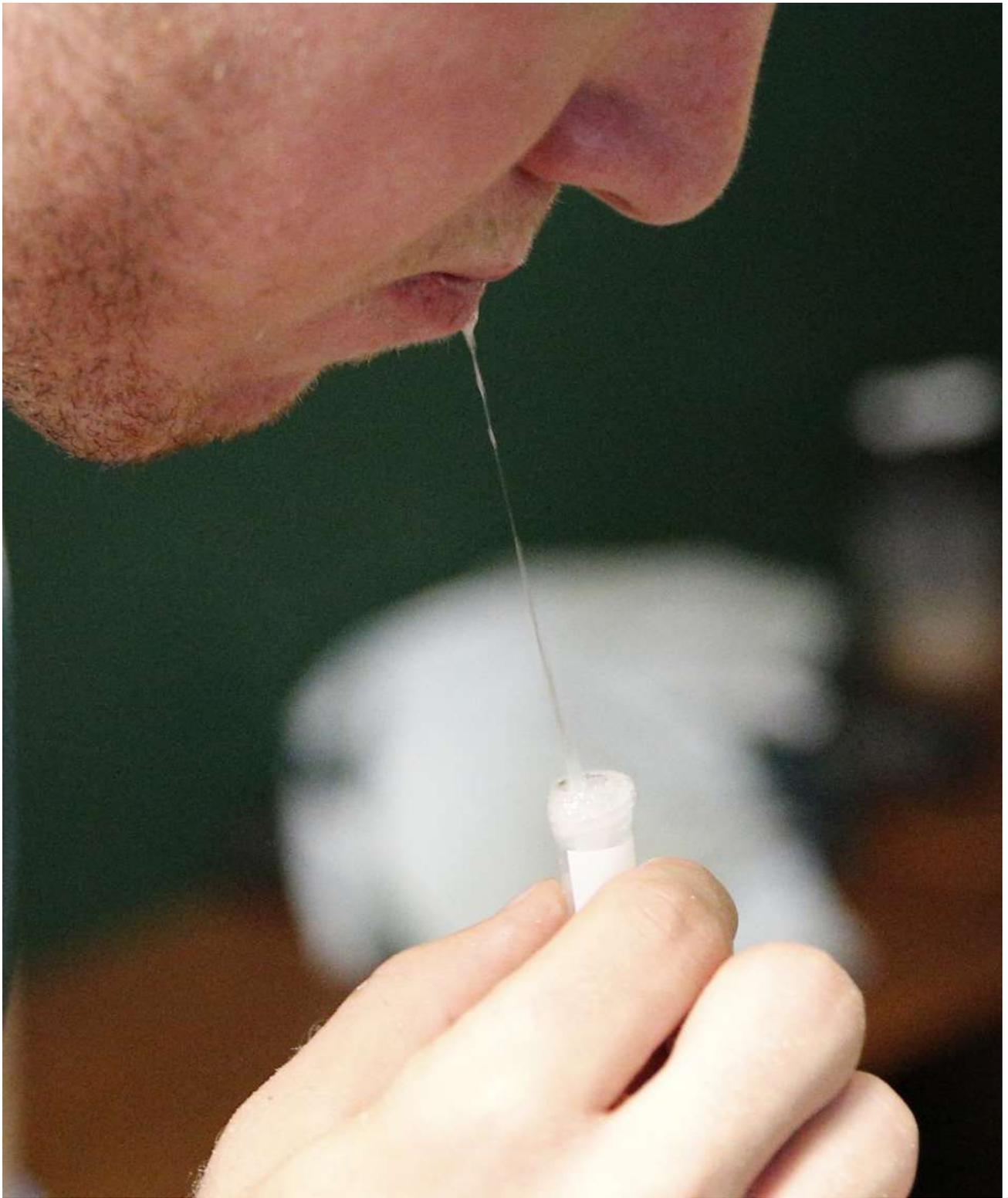
⁴ X2 Biosystems, Seattle WA www.x2biosystems.com

⁵ www.kingdevicktest.com

⁶ <http://bjsm.bmj.com/content/47/5/259.full.pdf>



Dr. Adrian Cohen is pioneering biomarker research in saliva at Randwick Rugby (*Photo: Ric McLallen*)



Randwick Rugby player provides a saliva sample (*Photo: Ric McLallen*)



Saliva samples are collected from Randwick Rugby players before and after games (*Photo: Ric McLallen*)



Saliva samples stored at -70 Centigrade in liquid nitrogen (*Photo: Ric McLallen*)

Randwick rugby get the gallop on pioneering concussion study

March 19, 2015 - 9:11PM **Rupert Guinness** Sports Reporter

<http://www.smh.com.au/rugby-union/union-news/randwick-rugby-get-the-gallop-on-pioneering-concussion-study-20150319-1m376p.html>

The Randwick rugby team will this year use the Shute Shield season, which starts on Saturday, to take part in a pioneering concussion research program in which all first-grade players will wear a biosensor to record impact levels in contact.

The program has been trialled in the United Kingdom and United States in various sports, but Randwick, who start their Shute Shield season against Eastwood at TG Millner Field, is the first Australian sports team to participate in it.

With the approval of the ARU, the program requires all Randwick's first-graders to be fitted for every game with an "X Patch" biosensor behind the ear to record impact levels in contact in both G forces and rotational force. A Randwick statement said the device, developed in 2007 by Seattle-based X2 Biosystems, "contains a low-power, tri-axial accelerometer (like those used in smartphones) with a 200g maximum reading and a tri-axial angular gyroscope".

The biosensor was first used by Randwick first-graders in a trial match against Manly at Latham Park last Saturday, but now they will continue to wear them for the entire Shute Shield season.

Dr Adrian Cohen, founder of NeckSafe and an expert in neck and head injuries, has lauded the device, which is about the size of a 10 cent coin and stuck on the player with special adhesive tape.

It is already being used in the UK by Saracens rugby club; while in the US, the sports that are using them include the National Football League, Major League Baseball, National Hockey League, Major League Soccer and US Lacrosse.



The technology: The "X Patch" biosensor will record impact levels in contact to help with research into concussion and other injuries. *Photo: Supplied*

"One of the things that interested me was the role of technology and actually getting some objectivity into what is going on," said Cohen when addressing the Randwick club season launch in Sydney on Thursday. "A lot of these things are subjective ... 'Did you see the hit? Was it a big hit? How is he playing? How is he feeling?'"

Cohen said head and neck injuries are inherent in contact sport and that research programs such as this one will help the community to understand and deal with them. "Head and neck injuries in sport are part and parcel of any contact sport," Cohen said. The biosensor won't detect concussion, but the data can be downloaded and paired with video of contact moments to provide knowledge of what leads to head injuries. "We need to understand what impacts are involved, what forces are transmitted to the head – both in 'G force' and in rotational force as well - which caused the damage," Cohen said.

The information, Cohen said, can be married to video and GPS technology "so we can see what is going on and get a firm understanding of the things that lead to injury and what we can do".

Cohen then reminded that: "In particular, it is not just the big hits and the obvious knock outs" that cause concussion.

According to the Randwick statement: "Players have been 'knocked out' by an impact as low as 40g, and walked away unharmed and with normal neurological tests after 180g, so there is considerable individual variation."



X2 Biosystems Introduces Their Next Generation X-Patch Pro Head Impact Monitor

March 3, 2016

At the 13th MIT Sloan Healthcare and Bio-Innovations Conference, which took place February 26th-29th, X2 Biosystems debuted their X-Patch Pro. The new wearable head impact monitor will replace their original X-Patch and will be released to the public in the second quarter of 2016.

The first generation X-Patch was released in 2012 and since then it has become widely used throughout the sports community. In 2015 it became the most tested wearable head impact monitoring device. In that same year multiple studies were conducted that showed by using the X-Patch during practices and games to monitor, then learn from the results, helped to reduce head impacts that lead to concussions by 30%-70%.



The device, which helps to monitor traumatic brain injuries and what impacts cause them over time, is used throughout the sports world and beyond. It is not just football players that are using these monitors in high numbers; as many in the United States still only associate head injuries with that sport. Athletes in soccer, baseball, Taekwondo, lacrosse, skiing, and many more use the X-Patch, as well as many military programs.



X-Patch Pro will build on the same monitoring system that proved to be so successful while making some very important changes and modifications. The Pro version is not only more technologically advanced, it is also lighter and smaller in size.

The Pro version continues where the original left off by encouraging use across a range of sports and activities; as it can be worn directly on skin or as a part of nearly any helmet or protective headgear. It records all head impacts and the data is then collected via Bluetooth technology where it is stored and analyzed in X2 Biosystems' Impact Management System App. The app can be accessed on tablets, Smartphones, and desktop computers. The data collected can then be viewed in real time to help coaches, trainers, and doctors understand the impacts.

The goal is to have the data be quickly accessible so it can help provide information and analytics that lead to actionable results. With the X-Patch Pro, X2 Biosystems, hopes they can reach more users than ever before.

X2 Biosystems CEO John Ralston wants to help change the conversation regarding head injuries. "We're excited about the launch of the X-Patch Pro because it enables an important shift in focus...to modifying athletes' behavior in a way that significantly reduces the risks and incidence of concussion injuries happening in the first place."

MORE INFORMATION: www.x2biosystems.com



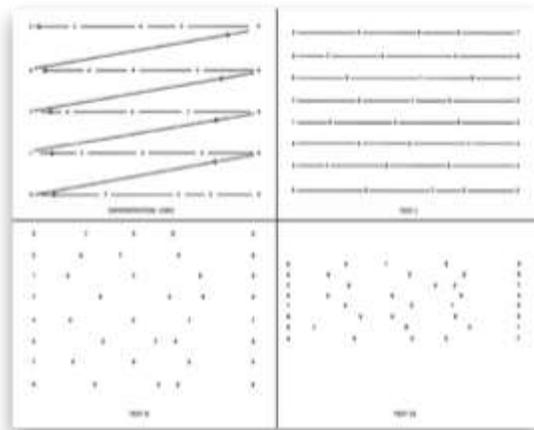
There's No Such Thing As A Tough Brain

The King-Devick Test is an objective remove-from-play sideline concussion screening test that can be administered by parents and coaches in minutes. The King-Devick Test is an accurate and reliable method for identifying athletes with head trauma and has particular relevance to: Football, Hockey, Soccer, Basketball, Lacrosse, Rugby, Baseball, Softball and All Other Contact and Collision Activities.

King-Devick Test is an easy-to-administer test which is given on the sidelines of sporting events to aid in the detection of concussions in athletes. King-Devick Test (K-D Test) can help to objectively determine whether players should be removed from games. As a result, King-Devick Test can help prevent the serious consequences of repetitive concussions resulting from an athlete returning to play after a head injury.

How King-Devick Test Works

Concussions are a complex type of brain injury that is not visible on routine scans of the brain, yet are detectable when important aspects of brain function are measured. King-Devick Test (K-D Test) is a two-minute test that requires an athlete to read single digit numbers displayed on cards or on an iPad. After suspected head trauma, the athlete is given the test and if the time needed to complete the test is any longer than the athlete's baseline test time, the athlete should be removed from play and should be evaluated by a licensed professional.



MORE INFORMATION: www.kingdevicktest.com