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**Northumbria
University
NEWCASTLE**

**EXPLORING THE USE OF WEARABLES
IN THE MANAGEMENT OF MILD
TRAUMATIC BRAIN INJURY**

D S POWELL

PhD

2022

EXPLORING THE USE OF WEARABLES IN THE MANAGEMENT OF MILD TRAUMATIC BRAIN INJURY

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BSc. MSc. MCSP. FFCI

Thesis submitted in partial fulfilment of the requirements for the award (Doctor of Philosophy) of the University of Northumbria at Newcastle.

Computer and Information Sciences

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Abstract

a) Why is the subject of your thesis important?

Every year more than 1 million people attend Accident and Emergency with mild traumatic brain injuries (mTBI), many of which arise from Sports Related Concussion (SRC). Despite the high incidence of such injuries, there is still no gold standard method to monitor the wide variety of impairments (cognitive, visual, motor symptom) accompanying mTBI. Accordingly, there is concern about the long-term effects of mTBI if diagnosis is delayed or missed entirely. Current reliance on subjective techniques such as symptoms are non-specific and an unreliable indicator of recovery, making it difficult to know when it is safe for players to return to play (RTP). This highlights the need for testing and validating the accuracy and applicability of objective tools to aid diagnosis, monitoring, and RTP protocols for individuals exposed to mTBI and SRC.

b) How have you undertaken the research?

I have taken a systematic approach to this problem-based research, starting by understanding the clinical challenges of mTBI from SRC where amateur rugby union is used as an exemplar for investigation throughout the thesis. Both mTBI and SRC is an under-researched area confounded by insufficient medical staff available to recognise SRC and monitor players within low resource (community) based settings. This may place these individuals at an increased risk of having a delayed diagnosis or it being missed entirely. My hypothesis tests if the use of digital technologies may enable affordable mTBI management, ensuring continuity and objective personalised assessment to support traditional approaches. Accordingly, my thesis broadly comprises of a literature examination and preliminary validation and testing, progressing to an in-depth exploration involving larger datasets and concluding with recommendations for clinical practice.

c) What are your main research findings?

My multidisciplinary approach reveals that focusing on one impairment in mTBI is unlikely to reveal meaningful insight to mTBI/SRC and RTP. Instead, multimodal digital technologies could enable affordable management, ensuring consistency and continuity (e.g., between assessors) while offering objective personalised data to better support traditional approaches. My results provide insight and identify the usefulness of instrumented walking (gait) as a digital (bio) marker for mTBI management. Based on receiver operating characteristics (ROC) and area under the curve (AUC) analysis free-living step velocity (i.e., walking speed) was the most sensitive (>0.72) at distinguishing healthy from acute SRC and may be useful for continuous monitoring and therefore informing SRC RTP.

In a purely computing science context, my findings have uncovered challenges and opportunities for further refinement. For example, there is still room for more 'no code' solutions in gait and algorithm analysis. Few clinicians would have the technical skillsets for completing free-living gait analysis. Therefore, validated algorithms within a "drag and drop", click and collect approach is needed to meet the recommend approach of remote, free-living monitoring of habitual behaviours. That is an important next step for the translation of academic research grade devices for broader deployment in clinical practice.

d) Why do your research findings matter

This thesis generally supports the suggested use of digital technologies as an affordable and objective method to support traditional approaches of assessment in mTBI/SRC. Passive and continuous monitoring solutions such as wearables are becoming ubiquitous in daily life. Moreover, the use of instrumented (lab) and free-living gait may fit that context with evidence of its use as a diagnostic tool. More work is needed to strengthen that claim as well as further investigate its use as a responsive tool. Identifying useful digital biomarkers in pathological cohorts such as mTBI may improve the detection of injuries and better inform safe (personalised) RTP guidelines. Identifying critical stages of recovery more accurately will also reduce the likelihood of premature return to play before full recovery, which is a necessary threshold in offering personalised care and rehabilitation. That is an important next step for the translation of academic research grade devices for broader deployment in clinical practice.

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Abbreviations

Abbreviation	Meaning
(\bar{x})	Mean
(a_v)	Vertical acceleration
(σ)	Standard deviation
°	Degrees
A&E	Accident and Emergency
ADL	Activities of daily living
AUC	Area Under the Curve
BESS	Balance Error Scoring System
CCS	Concussion consensus statement
CoM	Centre of Mass
COVID-19	Coronavirus disease
CT	Computed Topography
CTE	Chronic Traumatic encephalopathy
dB	Decibels
DHI	The Dizziness Handicap Inventory
DoD	Department of Defense
DWT	Discrete wavelet transform
FC	Final contact, when the toe leaves the ground
fmRI	Functional magnetic resonance imaging
f_s	Frequency
G	Gauss
GPDR	General Data Protection Regulations
GPS	Global positioning systems
G RTP	Graduated Return To Play
HIA	Head Injury Assessment
Hz	Hertz
IC	Initial contact, when the heel first touches the ground
iMEMS	Integrated microelectromechanical
ImPACT	Immediate Post-Concussion Assessment and Cognitive Test
IMU	Inertial measurement Unit
IoT	Internet of Things
K-D	King-Devick
L5	Fifth lumbar vertebrae
LEFS	The Lower Extremity Functional Scale
m/s^2	Meters per second squared
mA	milliamp
MANCOVA	Multivariate analysis of covariance
mBESS	Modified Balance Error Scoring System
mTBI	Mild Traumatic Brain Injury
NDI	The Neck Disability Index
NIH	National Institutes of Health
NSI	The Neurobehavioral Symptom Inventory
OHSU	Oregon Health and Science University
PCSS	Post-Concussion Symptom Scale
pET	Positron emission tomography

PIS	Participant information sheet
PoI	Point of Interest
RFU	Rugby Football Union
ROC	Receiver Operating Characteristic
RTP	Return to Play
SAC	Standardised Assessment of Concussion
SCAT5	Sports Concussion Assessment Tool 5 th edition
SRC	Sports Related Concussion
USA	United States of America
VA	Visual acuity
VAPORHCS	Veterans Affairs Portland Health Care System
VHA	Veteran Health Administration
VOMS	Visual Oculomotor Assessment

List of publications in thesis chapters (full list of publications & outputs please see Appendix 1)

Title: Sports related concussion: an emerging era in digital sports technology

Authors: Dylan Powell, Sam Stuart, Alan Godfrey

Publication Type: Journal Article

Publication Date: December 2021

Published in: Nature (npj) Digital Medicine

URL: <https://www.nature.com/articles/s41746-021-00538-w>

Title: Instrumenting traditional approaches to physical assessment

Authors: Dylan Powell, Yunus Celik, Diana Trojaniello, Fraser Young, Jason Moore, Sam Stuart, Alan Godfrey

Publication Type: Book Chapter

Publication Date: July 2021

Published in: Elsevier

URL: <https://www.sciencedirect.com/science/article/pii/B9780128189146000053>

Title: Investigating the AX6 inertial-based wearable for instrumented physical capability assessment of young adults in a low-resource setting

Authors: Dylan Powell, Mina Nouredanesh, Samuel Stuart, Alan Godfrey

Publication Type: Journal Article

Publication Date: November 2021

Published in: Journal of Smart Health

URL: <https://www.sciencedirect.com/science/article/abs/pii/S2352648321000428>

Title: Examining the use of wearables for remote monitoring of balance, gait and sleep in sports-related concussion: A single-subject study in rugby-union

Authors: Dylan Powell, Sam Stuart, Alan Godfrey

Publication Type: Journal Article

Publication Date: May 2022

Published in: Physical Therapy

URL: <https://academic.oup.com/ptj/article/102/5/pzac016/6534728>

Title: Wearables in rugby union: A protocol for multimodal digital sports-related concussion assessment

Authors: Dylan Powell, Sam Stuart, Alan Godfrey

Publication Type: Journal Article

Publication Date: December 2021

Published in: PLOS ONE

URL: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0261616>

Title: Exploring digital Sports Related Concussion (SRC) assessment performed by a single clinician

Authors: Dylan Powell, Sam Stuart, Alan Godfrey

Publication Type: Journal Article

Publication Date: May 2023

Published in: British Journal Sports Medicine

URL: In press

Title: Free-living gait does not differentiate chronic mTBI patients compared to healthy controls

Authors: Dylan Powell, Alan Godfrey, Lucy Parrington, Kody R Campbell, Laurie A King, Sam Stuart

Publication Type: Journal Article

Publication Date: May 2022

Published in: Journal of Neuroengineering and Rehab

URL: <https://link.springer.com/article/10.1186/s12984-022-01030-6>

Acknowledgments

The challenges of recovering from Concussion were really apparent from my playing experience as a university rugby union player in 2013-2016. This has been a driving factor and motivating factor for completing a PhD in computer science and mTBI/SRC. It has therefore been a privilege to for the past three years to work on a research topic that I am so interested in and impacts so many people each year. I would like to thank Department of Computer and Information Sciences at the University of Northumbria Newcastle for providing the opportunity to undertake this research training.

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Most importantly, to my family who have always been there to support me, and to my partner and fiancé Sophie , who has been there every step of the way of the journey- Thank You.

Declaration

I hereby declare that the work presented in this thesis has not been submitted for any other degree or professional qualification, and that it is the result of my own independent work. I also confirm that this work fully acknowledges opinions, ideas and contributions from the work of others.

Approval has been sought and granted by the University Ethics Committee on [June 2021] reference number 23365.

I declare that the Word Count of this Thesis is 45332 words.

Mr Dylan Powell

04/12/2022

Chapter 1: Understanding the challenges within mild traumatic brain injury (mTBI) management

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The article: *A range of perspectives for concussion management in men's rugby union*, was published as part of an invited blog in the **British Journal Sports Medicine** on **21 January 2021** (URL: <https://blogs.bmj.com/bjbm/2021/01/05/a-range-of-perspectives-for-concussion-management-in-mens-rugby-union/>).

1.1 Introduction

During my clinical training as a physiotherapist the challenges of diagnosing and identifying mild traumatic brain injury (mTBI) were very apparent. Often, the traditional tools and techniques used to assess my patients lacked the required sensitivity for accurate initial diagnosis or as prognostic indicators. Furthermore, although new approaches which could enhance clinical assessment (e.g., digital approaches) were being developed, they are often expensive and thus restricted to specific clinical settings with high resource allocation. This experience has been a strong motivating factor for my decision to pursue a multidisciplinary research-based doctorate/PhD that spans the computing and health sciences disciplines. By researching and evaluating modern approaches that integrate sensors, computing/data analysis in a health science setting, I hope to identify and integrate contemporary methodologies and technologies which could be used to improve mTBI management. My approach includes the exploration and investigation of more objective approaches to augment and enhance existing clinical techniques. Overall, I aim to contribute and add to the body of knowledge and innovation that will ultimately support and improve the quality of care delivered for those with mTBI.

mTBI (mTBI) is prevalent across a spectrum of cohorts/areas such as older adult fallers, young adults in road traffic incidents as well as contact sports such as rugby union [1]. For the purposes of this thesis, I have decided to focus on amateur level rugby union. The rationale being it is my passion and the area which has provided me with the most clinical exposure, where university rugby players are, at an increased risk of sustaining a mTBI [2]. Immediate and accurate (on-field) recognition and management of mTBI remain difficult even in professional teams/sports that often possess sufficient medical staff to monitor for suspicious mechanisms of injury which may lead to a mTBI. Thus, accurate recognition of mTBI is particularly challenging in environments with limited medical support such as amateur teams/sports, where there may be one coach or first aider only. This rationale is reinforced by new evidence highlighting the potential likely causative links of long-term impacts of inappropriate mTBI management and increased risk of neurological conditions such as motor neuron disease [3] and chronic traumatic encephalopathy (CTE) in retired players [4,5]. The long-term neurological deficits associated with head trauma have increased public health concerns (across many sports), driving demand for evidence-based monitoring/diagnosis and improved treatment [6]. Often in sport, mTBI is often described as sports related concussion (SRC) and terms are often used interchangeably. This chapter begins this thesis by highlighting some key challenges and contrasting perspectives across the spectrum of mTBI in rugby union.

1.1.1 *mTBI: In sports*

Some understanding surrounding the etiology and frequency of mTBI/SRC has increased in the last decade, but there is still a long way to go in providing objectivity in diagnosis and assessment. Timely and accurate diagnosis is important to ensure appropriate player management during recovery while informing any return to play (RTP) protocol after SRC. The management of mTBI is vastly different across sports and level of competition, with some sports having accelerated RTP protocols and different rules depending on which country the athlete resides. For example, in Scotland, based on current guidelines at time of writing, an adult rugby player may RTP 12 days post mTBI once s/he has passed through the graduated RTP [7]. In contrast, a player of the same age and level of competition in England would RTP after 19 days [8]. This discrepancy means a lack of agreement in expected recovery timelines which can be confusing for coaches, medical professionals and players for deciding when it is safe to RTP.

There are approximately 2 million registered players in England alone participating at an amateur level in rugby union [9]. Accordingly, it offers an opportunity to monitor a large pool of athletes who are at an elevated risk of sustaining a mTBI compared to the general public [1,10]. Furthermore, and importantly, it offers an opportunity to explore mTBI management in low resource settings where there may not be routine access to a (knowledgeable/specialised) healthcare professional to recognise mTBI signs and symptoms, and/or provide guidance on necessary approval for safe RTP after injury. To

explore current mTBI/SRC challenges, I start my thesis by examining contrasting perspectives to highlight pragmatic lines of enquiry arising from unmet clinical needs. Subsequently, I derive a suitable research hypothesis that will form the foundations of the research undertaken.

1.1.2 *Contrasting perspectives*

Here, a qualitative approach was used to gain insight into mTBI/SRC across a broad spectrum of participation. A semi-structured interview approach was adopted using open-ended questions to expose points of interest (PoI) that will underpin my research in this thesis. Language/text used here is generally representative of personal statements by the individuals providing their lived experience subjective thoughts (Figure 1) but tailored with the individuals to suit the requirements of a research thesis. The purpose of this undertaking is to highlight some of the current unmet needs pertaining to the challenges relating to mTBI management. Some key challenges are highlighted, evidenced by the italics text and PoI abbreviation.

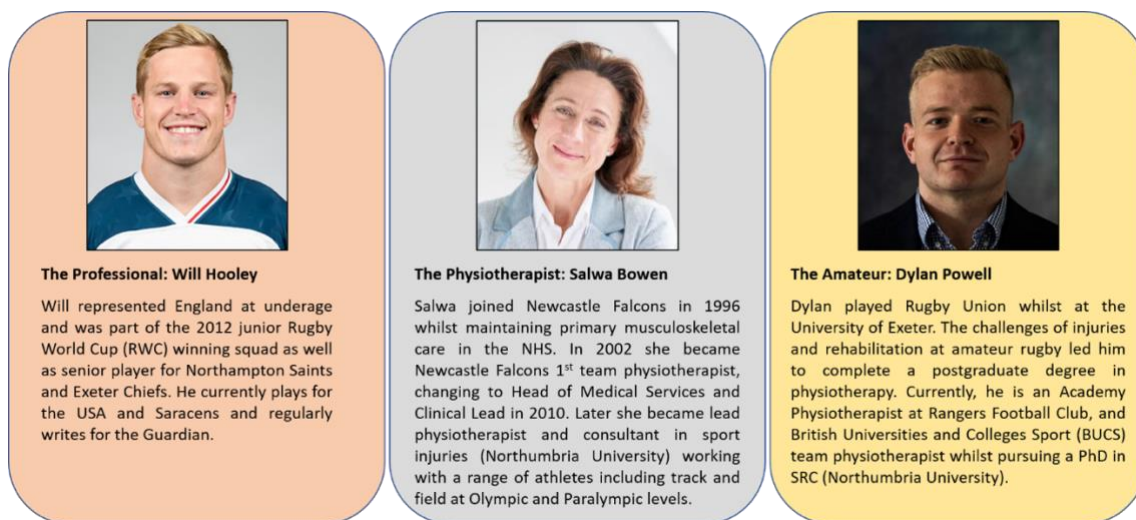


Figure 1. Contrasting professional experiences across the spectrum. Affiliations of those presented are at the time of conducting the work

1.1.3 *A professional rugby player (Will Hooley)*

1.1.3.1 *Perspectives within professional levels?*

To date, I think the level of detail surrounding SRC assessment has progressed dramatically and for the better. At the beginning of my professional career, it was restricted to basic pitch side or on field assessment. Inclusion of the Head Injury Assessment (HIA) protocol with tests such as Sport Concussion Assessment Tool (SCAT) and targeted neurocognitive testing has made the diagnosis and rehabilitation pathway far clearer for professionals [11]. All players in the top two (English) leagues (Premiership and Championship) are now required to study and complete a Rugby Football Union (RFU) concussion tutorial which educates players around the whole diagnosis, rehabilitation pathway and RTP. I feel players now recognise the seriousness of the injury far more than they did 5-10 years ago.

1.1.3.2 Can you give a brief outline of the management you received having sustained a SRC?

I sustained a SRC in the final 3-minutes of a game while representing United States of America (USA) against England at the 2019 senior Rugby World Cup. I was knocked out and have no recollection of the incident. To my knowledge the game was stopped, two doctors rushed on, and a stretcher was brought on after initial checks were done to my neck and head. I was taken off the pitch and straight to hospital.

I was then given a CT (computed tomography) scan to rule out a more severe damage to my head. The doctor in charge was a neutral match day doctor who assessed me and was there throughout the entire hospital assessment. Fortunately, I was discharged from hospital the same day. After the symptoms associated with concussion were resolved (3-days), I was able to complete a low intensity cycle on a bike for 20-minutes. After fully completing further SCAT tests, I got back to training. I re-did the SCAT tests again before being cleared to do controlled contact within training [11]. I missed the game against France but within 13 days I was back playing against Argentina. I saw the physiotherapist and medical team at least once a day right up until playing again.

1.1.3.3 What can be transferred into the amateur game?

The problem with the amateur game is lack a of *finance* (PoI1). What I described previously relies on money being spent to source needs. I believe that all clubs should get registered players to complete a baseline concussion assessment and there should be a medical professional at all levels of rugby matches. As a result of players investing time to complete a concussion assessment, and having a medical professional present, amateurs may take concussion more seriously. They will understand what they are dealing with and help their teammates to understand. They may then be more rigorous in their recovery and will recognise the importance of dealing with concussion.

1.1.3.4 What would you want all medics to know/appreciate for RTP post-concussion?

Due to a player being in the heat of the moment, it is important for medics to have the ability to override the player's emotion/willingness to stay on the pitch or RTP post-concussion. Due to the competitive nature of the player s/he will try and hide symptoms, feelings and even altering body language as processes very much rely on *how the player feels* (PoI2). Sometimes players push themselves too hard and lie about their symptoms to enable them to RTP. Alternatively, players can also overthink how they are feeling, making them feel worse than they are. Naturally, players want to continue playing/training and so medics must see through these.

1.1.4 Elite physiotherapist (Salwa Bowen)

1.1.4.1 Perspectives within professional levels?

Regular daily contact with either the doctor or physiotherapist at the professional level aims to identify and monitor any ongoing symptoms (or delayed symptoms) of concussion more closely. Appropriate action is taken as early as possible to manage the player. Earlier referrals are made to a neuroscience department with a consultant neurologist, who has an interest in concussion and is affiliated with the professional club. This helps minimize stress/anxiety and the potential psychological implications of the inability to compete without a time frame. Low mood and depression associated with being removed from play without a time frame, becomes part of the management plan with positive coping strategies being introduced much earlier in the management process.

1.1.4.2 Perspectives within amateur levels?

Recognise and remove is the protocol for management and identification of a potential concussion, based on a more cautious approach than any suspicion of concussion or identified head injury. The landscape in university sport is very different in SRC management from one club/university to another. *Daily contact* (PoI3) with a physio is almost impossible with a student athlete due to their other commitments. The player may be managed by *different practitioners* (PoI4) through the graduated RTP process and so there is no consistency within the clinical judgement on cognitive improvement. The *lack of consistency* (PoI5) can make the management of the more complex case concussions very difficult.

1.1.5 Amateur Player and physiotherapist (Dylan Powell)

1.1.5.1 What is your perspective?

There is a huge contrast to the professional level. Northumbria Rugby men's 1st team have had many concussions during the 2019-20 playing season, one of which occurred at an away game in Wales and required hospital assessment. I think the coach and player were in Accident & Emergency (A&E) for 12-hours before being seen on the Thursday morning. The alternative was to return to the northeast (7-hr coach trip), making it challenging to monitor the athlete and note potential deterioration. This is a common occurrence for players and BUCS staff.

Players often feel that when they are seen they are given general, non-specific *concussion advice* (PoI6) and discharged home, I think some players recognise concussion is a serious injury. However, most do not want to be removed from the play/training and are generally unaware of the potential damage they may be doing by playing on. Concussion is a difficult condition to identify and manage even in professional environments where there is access to specialised medical professionals or processes- highlighting how difficult it is at amateur level or low resource settings. Overall, there is a reluctance and barrier in amateur clubs to use the SCAT, as it carries significant administration burden, often takes significant time for players to complete which isn't always achievable, and is subjective in nature, which can't be relied on for diagnosis, so there is no incentive for players to take part (PoI7).

1.1.6 What is there to learn?

Firstly, the importance of education and communication on the significance of concussion. All elite level players are now required to undertake formal mTBI/SRC learning, appearing to be well received and respected in the professional game. There is demand for this within the amateur/university game and it must be more robustly conveyed to younger amateur athletes the importance of treatment and management.

Secondly, *resources* (PoI8) and *consistency* (PoI9) of approaches. Clearly there are differences in the availability of resources for professionals and amateurs, Table 1. Yet in terms of participation, professional and registered club players only represent a minority of players (6.5%) compared to the 1.9million amateur rugby players [12]. A rebalancing of resources may therefore be appropriate to increase medical provision for the amateur game. Equally, there is a real and pragmatic need to ensure there are *accessible/affordable* (PoI10) approaches for mTBI management.

BUCS (British Universities and Colleges Sport) Super Rugby is an amateur league, which is arguably operating at a semi-professional level as it aims to provide a pathway for aspiring professionals. Managing SRC in this competition raises many challenges but may provide opportunities to better facilitate our future understanding, diagnosis, and treatment of SRC in amateur and professional rugby. Typically, there is little daily or *consistent contact* (PoI11) with the same physio, which negatively impacts overall management. In general, there is a need to better understand the occurrence and dynamics of SRC because of the lower availability of medical professionals and

resources at this level. More emphasis should be given at all levels of competition to increase the objectivity in return to play and reduce pressure on returning to play quickly.

Table 1. Comparison of typical professional versus typical amateur medical cover

Match Day team	Professional	Amateur
Tournament medical manager	✓	✗
Match day doctor	✓	✗
Immediate care lead	✓	✗
Tournament team doctor	✓	✗
Pitch side ambulance	✓	✗
Teams own medical support	✓	✓
Lead physiotherapist	✓	✓
1 st Team Physiotherapist	✓	✓

Adapted from World Rugby Cup 2019, Minimum Medical Standards [13]

1.1.7 Defining a research hypothesis

This introductory chapter has provided a background into some of the common challenges within mTBI management from a sporting context. Here, a semi-structured interview approach was taken to understand the current unmet needs arising from contrasting perspectives relating to mTBI management challenges in rugby union on the pitch and from the sideline across the professional to amateur spectrum. Key PoI emerged, some of which were recurrent and had overlap: 1 *finance*, 2 *player feelings and confidence*, 3 *daily or regular contact*, 4 *different practitioners*, 5 *consistencies in assessment*, 6 *lack of objectivity*, 7 *lack of participation*, 8 *resources*, 9 *consistencies in guidelines*, 10 *accessible/affordable* and 11 *constant contact*. Subsequently for ease, those PoI were grouped according to three key overarching points for:

- PoI1: finance and resources,
- PoI2: access, scalability and consistency (inc. accuracy, subjectivity vs. objectivity)
- PoI3: personalised assessment and increased patient/player involvement

I propose that an exploration and a better understanding of those three PoI are necessary to inform contemporary mTBI management approaches. Thus, this leads me to my central hypothesis for my thesis:

The use of digital technologies may enable affordable mTBI management, ensuring continuity (e.g., between assessors) while offering more objective personalised assessment to support traditional approaches.

1.1.8 Thesis overview

This section provides an overview of my thesis, which is comprised of initial investigations (Chapters 2 to 5) and further contemporary mTBI analysis (Chapters 7 to 10). Specifically, Chapters 2 to 5 address the PoI's identified in Chapter 1, providing a springboard to more in-depth approaches to inform mTBI. The thesis builds towards an acceptance or rejection of my research hypothesis, Chapter 11.

mTBI arising from SRC in rugby union is used as an exemplar for investigation throughout this thesis. That is because amateur level rugby union is a large and under researched area with insufficient tools available to recognise SRC within low resource (community) based settings. I propose that a focus

on amateur university level rugby union can provide a good test bed to explore how PoI 1-3 can be addressed. Often, injury sustained in a community environment may be missed entirely or give rise to an increased likelihood of premature RTP before recovery. Accordingly, the thesis broadly comprises a literature examination and preliminary testing (chapters 2 to 5, with a recap in chapter 6), progressing to an in-depth exploration involving larger datasets (chapters 7 to 10) and concluding with chapter 11.

1.1.8.1 Chapter 2

Digital technologies span a plethora of hardware and software modalities. Consequently, there is a need to better understand what specific technologies could be of immediate and pragmatic use in mTBI management. In this chapter I will provide an in-depth critical analysis of the literature into both the traditional and more contemporary methods relating to mTBI/SRC. There will be a focus on assessment techniques to better understand the current state of the art, with a goal to harmonise key work within the field. That will shed light on research gaps relating to mTBI management and use of digital technologies. Some new findings and recommendations that emerge inform later work in this thesis e.g., remote monitoring of gait and a need for multimodal assessment.

1.1.8.2 Chapter 3

Upon highlighting some technological opportunities for improved mTBI management, this chapter investigates one data sensing modality. The work presented here provides an understanding of how a wearable approach can be used to offer contemporary data capture pertaining to the domain of motor assessment in mTBI. In this chapter, I undertook a wide scoping review to inform key technical details and skills utilised later in this thesis.

1.1.8.3 Chapter 4

This chapter presents the first of my two feasibility studies to address PoI1 and PoI2. Here, I explore the validity, usability and acceptability of an affordable inertial-based wearable to instrument motor-based tasks during a supervised assessment. This chapter also provides a preliminary exploration of gait to distinguish those with recent SRC history versus those without.

1.1.8.4 Chapter 5

This chapter presents my second feasibility study, addressing PoI3. Here, this study complements chapter 4 by going beyond a supervised assessment and use of the same wearable during remote, habitual mTBI assessment. This chapter is a single subject study/report of a player with recent history of acute mTBI. The purpose of this case study was to explore the feasibility and potential of the wearable to gather useful data remotely to better inform RTP.

1.1.8.5 Chapter 6

A recap of chapters 1 to 5, to take note of the acquired knowledge of how digital technologies could be used to address PoI's. From here, I springboard into a novel examination of mTBI assessment by undertaking a contemporary free-living approach.

1.1.8.6 Chapter 7

After understanding the scope and range of opportunities afforded by wearables and other novel findings from chapter 2, it was important to devise a protocol to inform a contemporary approach for mTBI assessment. Accordingly, this chapter details a comprehensive process for a more rounded and thorough mTBI assessment. The protocol is wide-ranging to generally inform the area of mTBI, but some of the suggested methods for analysis are purposefully excluded in later chapters to ensure clarity and focus within this thesis.

1.1.8.7 Chapter 8

After defining a multimodal digital assessment protocol, I explore the sensitivity of most approaches by comparing those with SRC history, no SRC history and acute SRC, The primary rationale being to explore gait as a diagnostic/distinguishing digital (bio) marker. This chapter also explores the practicalities and feasibility of conducting large scale multimodal assessment in the same cohort.

1.1.8.8 Chapter 9

This chapter explores the effectiveness of free-living instrumented gait as a digital *diagnostic/discriminative* (bio) marker by comparing chronic mTBI compared to healthy controls. This adds to the knowledge beyond acute mTBI free-living gait assessment, exploring gait in longer term mTBI sufferers.

1.1.8.9 Chapter 10

Findings from my literature inspire this chapter where I explore the effectiveness of free-living gait as an outcome to an intervention in those with chronic mTBI. Here, I explore free-living gait as the primary outcome measure of interest from the application of a pilot intervention for chronic mTBI rehabilitation. The aim here is to assess instrumented free-living gait as a *response* digital (bio) marker.

1.1.8.10 Chapter 11: Discussion, conclusion, and wider impact

The potential for wearables in healthcare is enormous but challenges remain, of which there are many. We detail here in Chapter 10, my conclusions from testing my hypothesis and the usefulness of wearables to inform SRC diagnosis. Additionally, I draw attention to sustainability which is often overlooked in comparison to the technical, professional, policy and social challenges. I believe that opportunities exist to drive sustainable implementation through wearables in clinical practice. I discuss sustainability in healthcare and later discuss more broadly how wearables could routinely enable (digital) medicine.

1.1.9 Impact of COVID-19

COVID-19 significantly affected my PhD topic and ability to conduct participant assessments. As there is significant close contact in team sports, amateur sports such as rugby union, was one of the last activities that were allowed to resume post COVID-19 social distancing [14]. No contact sport was played in Northumbria University until restarting after Summer 2021, which proceeded to impact the 2021-22 playing season. Additionally, this was confounded by hesitancy from the University to grant a formal resumption of my data collection due to definitions of essential research. Accordingly, that brought about many challenges and limitations, including a reduced opportunity to collect large data sets, outlined in my protocol (Chapter 7) across additional cohorts (e.g., Womens Rugby). To overcome, it afforded me an opportunity to adapt by creating new opportunities for data analysis and collaboration whilst COVID restrictions limited my primary data collection. This is exemplified by collaborations with Oregon Health State University to work collaboratively on equivalent and complementary datasets in mTBI.

1.1.10 Funding declaration

During my doctoral studies I applied for an A2 research grant (<https://ppef.org.uk/grants-awards/>) to the Private Physiotherapy Education Fund (Minerva House, Tithe Barn Way Swan Valley, Northampton, NN4 9BA). I was awarded £24,461 which was used to purchase wearable technologies that aided the research conducted as part of this doctoral thesis. The funder played no role in the design, conduct, or reporting of any of the work presented within this thesis.

Chapter 2: Digital approaches in mTBI assessment and monitoring

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The journal article “*Sports related concussion: An emerging era in digital sports technology*”, was published in the **Nature/npj Digital Medicine** in 2021 (URL: <https://doi.org/10.1038/s41746-021-00538-w>)

2.1 Introduction

Here, I investigate the current state of the art with digital technologies in mTBI with a focus in sport to provide context pertaining to affordable and pragmatic use in low-resource settings (Chapter 1). This chapter will begin to explore my hypothesis and is a scoping narrative review where I examine clinical assessment methods in four key mTBI components (cognitive, visual, motor, symptom), providing some insights to the translational utility of readily attainable digital methods. This chapter will aim to shed light on all PoI's. Accordingly, I examine common benefits and challenges facing those digital approaches as they aim to transition from novel technologies to efficient, valid, reliable, and integrated clinical tools. Lastly, I highlight future opportunities that attainable digital tools can have in mTBI diagnosis and monitoring (within SRC) with a systems science-based management approach including digital twinning and the 'digital athlete'. I support this with recommendations on how this field should develop.

2.2 Background

Direct impact(s) to the head or neck during sport are major contributors to individuals sustaining a SRC [11,14]. The incidence of mTBI/SRC has grown in many contact sports. For example, in rugby union the incidence can be as high as one concussion per game [15,16]. Accordingly, SRC presents notable health risks to those participating in contact sports where the intensity of e.g., high impact collisions are commonplace with considerable challenges in diagnosis and monitoring to inform RTP.

Timely identification of SRC is of critical importance to SRC management, to avoid adverse neurological implications [17]. Appropriate SRC management ensures participants do not RTP prematurely as this can lead to a secondary brain injury [15,18,19]. Second impact can have serious consequences including increased intracranial pressure and in extreme cases, death [20]. Hence, diagnosing SRC through timely and accurate assessment is of crucial importance to minimize short term health risks. This is reinforced by evidence highlighting the (potential) long-term impacts of inappropriate SRC management and increased risk of neurological conditions such as motor neuron disease [3] and CTE in retired players [4,5,21]. Long-term neurological deficits associated with head trauma have increased public health concerns (across many sports), driving demand for evidence-based monitoring/diagnoses, reduced exposure and subsequently improved treatment [6].

Immediate and accurate (on-field) recognition and management of SRC remains difficult. This includes professional teams/sports that often possess sufficient medical staff to monitor for suspicious mechanisms of injury which may lead to a SRC [22,23]. Thus, accurate recognition of SRC is particularly challenging in environments with limited medical support such as amateur teams/sports, where there may be one coach or first aider only (as highlighted in chapter 1). In rugby union environments with reduced medical provision, the conservative approach of '*Recognize & Remove and if in doubt, sit them out*' is adopted [24]. That involves permanently removing players identified as being involved in possible head injury related events (e.g., contact with head or neck) or if they display signs and symptoms associated with SRC there is no return to sporting activity until a medical assessment is performed. That aims to reduce occurrences of missed or misdiagnosed SRC in low resource/amateur environments.

SRC presentation is heterogeneous with a wide variety of signs and symptoms, some of which are subtle/undetected and easily missed or may only become apparent in the following hours and days after injury [25]. Therefore, challenges remain in the subsequent (off-field) monitoring and RTP protocols following SRC and during recovery. This is confounded by traditional approaches used to diagnose and monitor SRC often occurring during infrequent snap-shot assessments. The most widely used approach in SRC assessment is the SCAT which tests aspects of cognition, balance and vision via a paper-based questionnaire administered by a health professional [19,26]. The manual but subjective nature of tests like SCAT, means formal SRC diagnosis, rehabilitation and RTP is based solely on clinical judgement with information gathered from self-reported assessment techniques [27]. This is problematic as research shows SRC is a dynamic and complex pathological process with difficulty to

measure impairments that can change or deteriorate rapidly without any prior indication [28]. This presents challenges for safety, rehabilitation and RTP.

The Concussion Consensus Statement [25] does not stipulate or provide any differentiation on the severity of injuries nor understanding of the intrinsic processes that may be associated with SRC. This lack of guidance and direction reinforces a need for more objective approaches through robust development and provision of diagnostic and prognostic digital biomarkers to better assess the presence/severity and recovery of SRC, respectively. Digital imaging technologies such as functional magnetic resonance imaging (fmRI) or pET scanners are (reference standards) already used to assess the severity of damage such as skull fractures and bleeding on the brain in more severe traumatic injuries. However, their effectiveness and practicality when used in isolation for SRC diagnosis or diffuse axonal injury is yet to be proven, with only a minority of mTBI such as SRC displaying distinguishable structural changes immediately post-concussion [29]. Additionally, not all players suspected of SRC require hospital assessment and of those attending Accident and Emergency (A&E) Departments, only those presenting the most severe signs and symptoms will be sent for imaging [30–32]. Thus, those reference imaging technologies are not typically deployed or offered for routine SRC assessment.

Recently, lower cost (digital) noninvasive technologies have been developed to measure and monitor outcomes for more informed assessments [33]. Such approaches could provide scalable robust data for more informed and integrated SRC diagnosis to better inform RTP, enhancing the efficiency and precision of healthcare assessment [34,35]. In this narrative review, I examine SRC clinical assessment methods in four key areas (cognitive, visual, motor, symptom), providing insights into the translational utility of readily attainable digital methods. I examine common benefits and challenges facing those digital approaches as they aim to transition from novel technologies to efficient, valid, reliable, and integrated clinical tools for SRC. From a synthesis of the literature, I highlight future opportunities that attainable digital tools can have in SRC diagnosis and monitoring with a systems science-based management approach including digital twinning and the ‘digital athlete’. Before concluding, I provide recommendations on how this field should develop.

2.2.1 Sports related concussion assessment

The rise in mTBI from SRC cases presented at A&E has prompted closer discussion about improved assessment and management, including calls for development of national guidelines [30]. Mistry et al [32] highlight the main objective of SRC assessment in A&E is to triage the player/patient, identifying any readily obvious brain injury symptoms/signs that require e.g., surgical intervention. That approach, although it may improve efficiency, omits thorough assessment of many other subtle SRC impairments such as cognitive, motor/functional (e.g., balance, gait) and visual deficits [36]. Thus, current SRC assessments are often binary snapshots, ignoring the interconnected nature and heterogeneity among individuals. Most post discharge management involves information for the player regarding red flag signs/symptoms and/or provision of head injury information leaflets. Furthermore, outside of professional environments, there is often no enforceable physician assessment or follow-up until returning to full contact training [37].

As such current SRC management and rehabilitation protocols rely on self-reported measures/symptoms to determine readiness to play. Therefore, SRC recovery times and prognosis are highly variable and varies dramatically across different age groups and gender. Indeed, some individuals can take significantly longer than the expected to RTP (3-4 weeks) and experience chronic symptoms even after returning to play [38,39] As such reliance on subjective non-specific measures such as symptoms make it extremely difficult to confidently know when it is safe for players to RTP. This highlights the need for valid, objective tools to aid diagnosis, monitoring, and RTP in SRC [32].

2.2.2 Cognitive assessment

2.2.2.1 Routine clinical approaches

Comprehensive assessment of cognitive function outside of sport typically includes detailed interviews, exploring the history of a patient's health, education and social background. In contrast, SRC focusses on more specific areas of cognitive functioning only such as short-term memory, working memory and executive-level function [40]. Pen-and-paper tests include the Short-Blessed Test, digit span (forward and/or reverse) and the Standardised Assessment of Concussion (SAC), now incorporated into the fifth version of the SCAT. Despite widespread clinical use, these tests carry considerable challenges including manual score calculation hindering automated or immediate comparison of scores across different individuals and time points [41]. Fortunately, progression to using digital neurocognitive testing has overcome some of these limitations.

2.2.2.2 Digital approaches: Computerised programs

The introduction of digital-based cognitive assessments offers several advantages over pen and paper methods including objective cognitive metrics (e.g., reaction time calculation), randomization of test trials with automation of data collection and analysis [42]. Immediate Post-Concussion Assessment and Cognitive Test (ImPACT) is an example of a scalable computerized neurocognitive tool that assesses verbal memory, reaction time, visual-motor speed and visual memory [43,44]. ImPACT tests are complemented with the integration of demographic data and a post-concussion symptom scale for players and staff. Research shows ImPACT is sensitive post-concussion in the acute phase (within the first few days) with measurable differences in verbal memory, visual memory and slower reaction times [45,46]. However, there is mixed evidence for neurocognitive testing in subacute and chronic concussion [16,37,47]. Indeed, the international consensus statement of concussion states that “tests should not be seen as the sole basis for the management of decisions” [17].

Despite the value of digital neurocognitive testing in acute SRC cognitive testing, challenges remain for pragmatic deployment in low-resource environments. High cost of initial software licenses or fixed yearly subscriptions can be prohibitive to amateur sports teams with limited budgets. Often these commercially orientated companies rarely permit independent validation of their technologies or algorithms used to interpret raw data or outputs. This lack of open-source or transparent approach makes it very difficult for governing bodies to make evidence-based decisions about which test or technology to endorse/promote. Another pragmatic limitation on a single approach is the reliance on baseline data, where it isn't always feasible to gather pre-injury data due to e.g., players moving between clubs/teams. Without baseline information, it is difficult to ascertain if an athlete's post-concussion neurocognitive scores are the result of concussion or individual variability. Consequently, no single cognitive test/technology has proven capable for standalone use. This has placed greater responsibility on clinicians to have prior experience and use clinical judgement when managing SRC (13,33), which may partly explain the reluctance to adopt technology in SRC assessment.

2.2.3 Visual assessment

2.2.3.1 Current approaches

Normal vision correlates with healthy cerebral activity and brain function [48]. SRC can cause impairments in visual and oculomotor speed, with research showing oculomotor dysfunction present in up to 90% of SRC cases [49]. Traditional subjective visual assessment includes eye-tracking tests e.g., Visual Oculo Motor Assessment (VOMS), which assesses impairments via self-report. This test includes a baseline measurement where players verbally rate changes in headache, dizziness and nausea symptoms compared with their immediate baseline state on a scale from 0 (none) to 10 (severe) to determine if each test provokes symptoms [50]. Other visual tests include the King-Devick (K-D), which is an indirect measurement of rapid eye movements, language function and attention. The K-D

test has demonstrated moderate sensitivity (60%) but poor specificity (39%) in identifying players diagnosed with SRC [47]. It is also unclear how training and learning effects can influence participant scores, and to date there is an absence in clinically significant change scores/data. Indeed, a recent paper outlined that current eye tracking tests (such as K-D) were no better than traditional off-field screening alternatives [47]. This is confounded by deficiencies and heterogeneity in current cognitive testing protocols and environments, making comparisons between studies and decision on choice of test difficult [46,51]. As such the paper advised that current tests should not be routinely incorporated in SRC assessment.

In addition to suboptimal sensitivity, current tests rely heavily on baseline data collection which are not feasible to implement in low-resource environments, where there is often insufficient staff/funding to perform baseline screening. Hence there is significant demand for more sensitive, objective and scalable solutions for visual assessment in the form of wearable digital eye trackers and/or mobile technologies.

2.2.3.2 Wearable digital eye-trackers

Non-invasive digital technologies such as eye trackers can objectively monitor eye movements during laboratory tasks, assessing visual and cognitive processing [48,52] in a variety of research paradigms ranging from neuroscience to social science [53]. Despite this rapid rise in availability of technologies, there are several barriers to clinical deployment. Stuart et al [54] outlined current state of the art and challenges in mTBI visual assessment, finding most studies do not adequately address or report validity or reliability of eye-trackers, making comparison or clinical interpretation difficult. To translate these technologies into clinical application there is a need for more routine validation, standardization in testing paradigms and transparency on their use, including algorithms and data analysis methods. [55,56]

For the few studies with adequately reported information, Khalife et al highlight the benefits of investigating rapid, reliable eye movement impairment in SRC assessment with the Tobii eye-tracker [57]. The latter shines a light onto the eye causing a reflection, a high-resolution camera then captures an image of the eye with reflections which is then used to calculate gaze direction. Research has found the accuracy of the Tobii EyeX to offer sufficient accuracy and precision in gaze direction [58]. This is consistent with research testing other technologies such as Eye-Sync which offer good-excellent levels of sensitivity (88%) and specificity (87%) in smooth pursuit assessment [59,60]. Overall digital technologies offer high-resolution quantitative data and value over traditional approaches such as VOMS. Despite promising results of accuracy in academic research, there has yet to be clinical research investigating thresholds or measures that can be applied into a meaningful change that can be widely used for SRC assessment.

2.2.4 Symptom assessment

2.2.4.1 Current approaches

Despite rapid and extensive development in the availability of different tests to assess SRC, the symptom checklist and severity indices are retained as the cornerstone for most decisions around readiness to return to play. This includes the Post-Concussion Symptom Scale (PCSS), which assesses a variety of symptoms (0-6 of increasing severity) to give an overall score and has been adapted and abridged into SCAT5 [66,81].

Although common due to their ease of use, studies have examined the sensitivity of symptom scales in SRC and found suboptimal sensitivity and specificity [66,67,81]. Moreover, the severity of symptoms/signs reported by players following a SRC varies significantly (immediate or delayed onset) which can hinder confidence for clinicians and players/patients when assessing readiness to return to play [66,82]. Additionally, some studies report that players can manipulate self-reported baseline symptom scores, allowing them to mitigate any poorer performance of scores post-concussion [83]. For

example, only 17% of athletes self-reported symptoms of SRC, although nearly half of this cohort (48%) sustained a head injury and associated signs of SRC [83]. Relying on self-reported data may be particularly challenging in competitive environments where there is societal or financial gain in staying injury free.

Alongside the challenges of subjectivity in self-reported symptomology there are significant practical and logistical barriers. Current pen-and-paper based SRC assessment methods can take 10-15 minutes/player which isn't always achievable in environments with only one medical practitioner to complete player assessment (e.g., at an amateur level) [84]. Therefore, challenges remain in providing approaches to more efficiently document SRC injury characteristics across both low- and high- resource environments. The growth in usage and availability of smartphones and affiliated commercial digital technologies means players and clinicians already have widespread access and familiarity of use. A move towards mobile digital applications may serve to overcome some limitations of symptom assessment, data storage and analytics compared to self-reported pen and paper methods.

2.2.4.2 Digitally recorded symptoms

Several smartphone/mobile digital applications/apps are available to track injuries and monitor SRC recovery through symptom reporting. Apps include CSX (used by e.g., World Rugby) and the Cleveland Clinic Concussion Application (C3) which records data on reaction time, memory, vision and information processing [77]. To my knowledge, CSX has yet to be fully deployed into amateur sports. However, C3 has been used to collect some concussion data in college and professional rugby [67]. Linder et al found that use of an Electronic Injury Reporting app provides a useful digital platform for injury related demographic analysis [67]. App advantages include the capacity for players to complete (in their own time) symptom recording as frequently as required with more regularity and consistency in the absence of clinicians.

Current reliance on traditional non-digital approaches such as the SCAT5 and lack of robust databases means the progression and recovery of SRC symptoms is unclear [20,48]. Moving towards digital symptom recording may allow greater understanding and co-investigation with other SRC impairments.

2.2.5 Motor assessment

2.2.5.1 Balance and gait under direct observation

Balance and gait/walking impairments are associated with neurological conditions, including concussion and therefore form a key component of clinical assessment [19,61–63]. The Balance Error Scoring System (BESS) test is a balance and postural stability assessment that is widely used for examining impairments by asking participants to adopt specific stances aimed to challenge their motor and vestibular system [64–66]. However, the BESS is assessed subjectively, through manually recording errors (e.g., if the participant removes a hand from their waist during a single leg stance) and timed using a stopwatch. Consequently, the BESS sensitivity is greatly influenced by assessor experience and research suggests only sensitive in the acute phase (within first 2 days of injury) [67]. These inherent limitations of subjective assessment make it difficult to apply in sporting environments, where there is demand for precise and sensitive clinical measurements. As outlined by Johnson et al, traditional balance assessments 'are subjective in nature, do not adequately challenge high functioning athletes and may not be capable of detecting subtle balance disturbances following a concussive event' [68]. This raises questions surrounding the accuracy in diagnosis, RTP protocol and crucially, paradigms by which SRC is assessed. Indeed, gait (and other motor tasks) deficits may in fact be impaired for long periods beyond typical timeframes of recovery[69,70]. Therefore, traditional assessment of motor function carries significant limitations yet remain extremely prevalent across clinical practice. Opportunities for improvement may be afforded by adopting digital approaches such as inertial sensor-based wearables discussed in the next section.

2.2.5.2 *Inertial sensor-based wearables*

The development of wearables equipped with inertial sensors (accelerometers and gyroscopes) has facilitated pragmatic instrumented testing of traditional approaches such as the Timed-Up-and-Go (iTUG) and BESS [62,71,72]. These studies do show attempts to instrument traditional tests and provide objective digital SRC biomarkers from a single wearable sensor. Recently, Celik et al [73] adopted a multi-wearable approach towards a comprehensive instrumentation of SCAT5. By using eight inertial wearables (wrists, legs, lower back) to segment specific components (e.g., tandem walk and static balance) a wealth of spatial and temporal data associated with each SCAT5 component with excellent/millisecond resolution. Moreover, the study showed how wearables can automatically and more accurately calculate, recognize balance and gait errors during tasks compared to clinical observation, also highlighted by Johnston et al [70,74]. Beyond instrumentation of traditional assessment, research with inertial wearables shows SRC and mTBI impacts balance, gait and turning [67,75–78], including under longitudinal assessment [67].

Despite laboratory research showing motor impairments can be strongly associated with SRC, it is not yet known exactly what clinical gait (or turning) assessment techniques are sensitive for SRC. Therefore, barriers remain in clinical validation and how to translate some novel inertial measures (e.g., frequency-based data) into clinical endpoints or biomarkers. Indeed, the episodic nature of current laboratory assessments may be supplemented beyond the clinic/hospital during real world/free-living remote assessment [79,80]. However, a necessary precursor to longitudinal free-living remote balance and gait assessment is verified and validated digital SRC biomarkers enabling trust and better understanding by clinicians and patients [55].

2.2.6 *Towards daily use of digital approaches*

Digital approaches and technologies could provide objective information, generating useful and reliable data for improved data presentation, analysis, and insights for SRC management. From this narrative review, Figure 2 presents a hypothetical scenario contrasting traditional (2A) to digital (2B) approaches for cognitive, motor and visual assessment. Figure 2A alludes to current limitations e.g., different clinicians performing assessments in highly controlled and supervised environments, which may not be representative of normal behaviour. Figure 2B demonstrates how digital-based assessments could facilitate integration from multimodal sources (technologies, inc. wearables). Multimodal assessment is not a novel concept in SRC assessment. However, it often still focusses and relies on assessment under observation with non-portable technologies such as fMRI and lab based neurocognitive assessment [87,88]. Moving to a low-cost and portable multimodal digital approach could capture e.g., behavioral trends continuously and remotely in habitual environments without the need for a clinician to be present. Figure 2C. By adopting complementary digital approaches, more objective comparisons or insights could be made across a range of SRC impairments (cognitive, visual, symptom and motor).

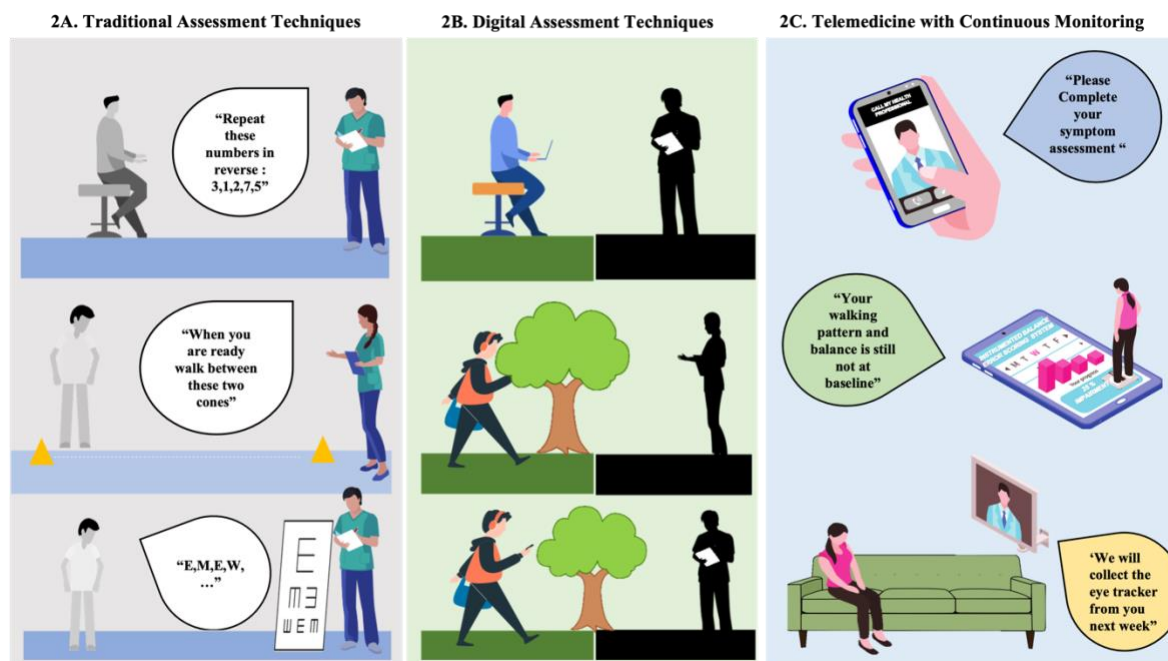


Figure 2: Contrasting traditional to digital approaches

2.3 Discussion

Implementing digital approaches in sports medicine and SRC care could transform how player data is captured, analysed and communicated. Current SRC approaches are restricted by the reliance of subjective self-reported assessment under direct observation of a clinician. Thus, outcomes are often reliant on a player informing the clinician and the clinician’s clinical judgement or interpretation. Objective approaches in SRC are often confined to bespoke or professional environments, limiting deployment and accessibility to amateur or adolescent players. Additionally, there is considerable focus on traditional in person assessment at episodic ‘snapshot’ assessments with little to no remote/habitual data collected on those who sustain a SRC during contact sports. The addition of digital or remote assessment approaches such as wearables may augment, and supplement data gathered in traditional assessment visits under supervision of healthcare professionals.

Presently, digital cognitive testing only offers a snapshot assessment. Yet, testing could be better utilized through constant remote evaluation via apps. This would mitigate the need for clinicians to be present and would allow higher frequency of testing within the player's routine environment [89]. Although testing in the latter would be conducted in less controlled conditions, there is considerable value in conducting testing in remote, real-world/free-living as they would be within habitual conditions [34,90,91].

Use of current eye tracking approaches in SRC is not currently supported. However, there are opportunities for use of digital eye-tracking outside of the clinic or in static situations. As these methods do not require active participation of the wearer, they overcome many potential issues of adherence allowing participants to wear these technologies as part of their daily life [34]. However, capturing reliable data on impaired eye movement outside of controlled/laboratory conditions generates many complications. Thus, challenges remain in the refinement and optimization of eye-tracking as a future SRC diagnostic tool. These include minimum and maximum testing times, choice of eye tracking tests, lack of standardized protocols to detect SRC eye movement impairments as well as complexity of analyzing big data. Overcoming these challenges will require development and refinement of protocols and data processing methods/algorithms.

Symptoms post SRC are thought to be closely linked to improvements in physiological recovery and should therefore remain a cornerstone of assessment [92,93]. However, digital monitoring may not easily lend itself within free-living due to requirement for players attention. Yet by collecting longitudinal (habitual) symptom data, a deeper understanding of the rate of progression of symptoms could be determined, supporting the transition and deployment of other digital approaches. Clinicians could deploy apps to measure symptoms beyond snapshot testing points but would need to account for testing conditions. Adoption of mobile technologies to support symptom documentation would allow integration with other digital approaches, providing holistic systems-based approaches to SRC management. If used routinely, such approaches may have capacity to provide alert systems to healthcare professionals for missed SRC or injuries within squads, which could standardize and systematize injury severity through evaluation of red flags via structured and personalised assessment.

Use of inertial movement unit (IMU) based wearables within mTBI have shown considerable promise for measuring balance and gait impairments [73,81,94–96]. *Yet the true utility of inertial technologies may be their use beyond the clinic with provision of habitual balance and gait data* [85]. Such wearables should become more accepted and the standard for gathering continuous, high-resolution free-living data due to their discrete attachment and low wearer burden. Technical validation of inertial wearables has led to the development of a conceptual gait model [97], providing a framework for clinicians to better utilise gait data to make more informed clinical decisions. For example, a similar modelling approach [95] has been applied in chronic (non-sporting) mTBI providing enhanced lab-based gait analysis, which could be a means to better understand underlying impairments and/or assess response to interventions.

Accordingly, this thesis will apply and evaluate gait in acute and chronic mTBI/SRC from free-living gait data to provide better insight to habitual player recovery, better informing RTP.

2.3.1 *Towards the digital athlete*

Measuring and monitoring a single impairment is unlikely to reveal meaningful new insights into SRC. There is a need for a multidimensional/multimodal approach with digital e.g., diagnostic or response models/frameworks to improve outcomes [98,99]. Therefore, step changes to understand, diagnose and manage SRC will require multi-scalar approaches which could be built around a systems-science framework to shift research into practice. Achieving this will require cross-disciplinary collaborations and the adoption of novel approaches with shared repositories to facilitate and intensify collaboration.

One emerging concept is digital twinning, a strategic technology made feasible through developments in the Internet of Things (IoT) and big data. It has been applied to complex systems and in medicine to provide a framework to create a virtual representation of players based on the integration of data from digital devices, omics, imaging, and electronic medical records [100]. A digital twin can represent a back-up/copy to a person's physical state before an intervention, providing retrospective or real-time monitoring of a wide range of parameters [101]. The application of wearables to create a digital twin of baseline health information for a player participating in contact sport would provide objective data, providing opportunities for remote monitoring and evaluation [102]. This leads to the concept of the digital athlete (Figure 3) where an open framework is proposed for the emerging areas of digital health [102]. The ubiquitous nature of IoT/digital technologies coupled with digital twinning offers the potential for a paradigm change to better understand mTBI and more effective detection, prediction, and assessment of SRC. However, digital twinning is not just about collecting data, it is also about creating the computing architecture allowing new insights to support decision making, synthesizing information, facilitating communication and the development of shared hypotheses [103]. Incremental changes in the ability to gather data to generate digital biomarkers related to health would enable the creation of player centric protocols and targeted treatments. Central to this development has been the recognition that wearables are now part of IoT systems, incorporating sensing with data

analytics to create an integrated approach, providing insights into physiological status, health and performance [101,104]. Built on the concept of digital twinning, the digital athlete would enable better integration of data, simulation of scenarios and predict outcomes more accurately for SRC assessment and monitoring.



Figure 3. Digital technologies can enable the digital athlete.

2.3.2 Future considerations for the field

Digital approaches could have tangible objective improvements in SRC diagnosis and monitoring. However, there are notable application and deployment challenges pertaining to sports (individual versus team), funding, environments (professional and amateur) and education. This will demand different approaches to ensure correct adherence and implementation as well as robust data collection protocols to ensure adequate monitoring. Likewise, there are privacy (security), ethical (remote and/or continuous monitoring) and trust considerations (effectiveness of digital technologies to augment traditional approaches) when collecting SRC data. To better understand these demands, there is a need for independent and multidisciplinary research with diverse stakeholders (e.g., athlete/patient, clinician, technologist, and sport’s governing bodies) with transparency in findings and conclusions drawn. To support behaviour change for routine digital adoption in SRC, there must be development of multidisciplinary standardized frameworks and agreement in validated/reliable tools to ensure technologies are trustworthy and fit-for-purpose.

Digital-based approaches coupled with novel concepts/frameworks from other research domains (e.g., digital twinning) could provide a persuasive and timely route to addressing ongoing mTBI limitations in SRC (and elsewhere). General recommendations provided here could help modernize (digitize) mTBI diagnosis and monitoring to e.g., protect athletes and their sport. Accordingly, high level recommendations include:

- Development of multimodal open-source athlete digital monitoring approaches for routine integration into low resource settings
- Transparency of all digital tools in SRC assessment (i.e., no black-box development)
- Routine engagement with sport specific stakeholders on how digital tools could advance SRC diagnosis and monitoring,
- An expert, multidisciplinary consensus on use of fit-for-purpose digital SRC tools within and/or across sports

2.4 Conclusions

This chapter highlighted the increasing incidence of mTBI from SRC and challenges of current diagnosis approaches has illuminated the scale of the problem for routine diagnosis and monitoring. Shortcomings posed in Chapter 1 are further evidenced here, as although traditional (and subjective) approaches will remain a crucial component of SRC assessment, they are unable to reliably provide an evidence-based approach to the management of mTBI, certainly within a SRC context to inform RTP and supporting PoI3.

The literature gathered in this chapter offers some credence to my hypothesis (Chapter 1), that digital approaches may have the potential to transform the way data can be objectively captured under direct observation. That includes the way data is processed and analysed, enhancing current mTBI management. Of note there is the greater need for open-source approaches, which could help achieve affordable, scalable and objective approaches in mTBI management (PoI1 and PoI2). Progression to habitual (e.g., gait) assessment could be a suitable mechanism to develop a personalised approach in mTBI management while indirectly increasing assessment participation through passive monitoring (PoI3). Moreover, digital technologies could enable multi-modal approaches to enable the gathering and analysis of data efficiently through novel engineering and computer science approaches.

This chapter has found that instrumented free-living gait could be a novel digital (bio) marker with *diagnostic* (i.e., identify mTBI) and *response* (i.e., establish effectiveness of intervention) capabilities. Accordingly, the next chapter will establish a baseline understanding of current approaches in gait assessment. Exploration will continue with the focus on inertial wearables for instrumenting gait, including technical considerations. There will be a focus on principles relating to inertial technologies for use in this under researched but potentially high reward topic which could be used to assess RTP as well as inform rehabilitation. (Later chapters will use the knowledge in chapter 3 to instrument gait under various conditions.)

Chapter 3: Instrumenting motor assessment: Gait

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The article appears as a book chapter (*Instrumenting traditional approaches to physical assessment*), appearing in the book **Digital Health: Exploring the use and integration of wearables** published by Elsevier (URL: <https://doi.org/10.1016/B978-0-12-818914-6.00005-3>). Permission granted to freely use the whole chapter with declaration of authorisation included in Appendix 3.

3.1 Introduction

After understanding the current challenges in mTBI management, here I detail how an inertial-based wearable technology can be used to instrument one of the four components within mTBI management, motor assessment. I suggest that inertial wearable developments (evidenced in other clinical cohorts) could be utilised for the purposes of this thesis to improve mTBI assessment. The work presented here provides an understanding of how inertial wearables can be applied to capture motor tasks of interest to mTBI management e.g., gait. More generally, this chapter showcases how digital-based instrumentation could aid clinical deployment with practical steps in wearables, signal processing, feature extraction, clinical tasks with reference to the clinical, analytical validation and verification of novel approaches.

3.2 Evolution of physical assessment

Traditional approaches to movement assessment have involved subjective manual observation in controlled clinical environments. Typically, a physiotherapist will use their clinical expertise to determine any limitation from the task/test that is being conducted. For example, physiotherapists will observe their patients who may have motor limitations due to a neurological disorder (e.g., stroke) as they perform a short walking task to get a better understanding of their ability to perform activities of daily living (ADL). By studying and understanding ADL motor tasks the health-care professional can also extrapolate their opinion to determine the patient's quality of life which may be impaired due to reduced mobility [105]. Subsequently, rehabilitation strategies could be developed with the patient to aid their daily activities (e.g., walking), thereby improving their mobility and ability to function optimally.

The benefit afforded to the patient from observational testing is obvious, bespoke feedback from one-to-one consultation with a trained healthcare professional. However, there is one obvious limitation: the expertise and clinical experience from one healthcare professional to the next can vary greatly due to training, longevity in their field or lack of exposure when treating and assessing different pathological conditions. Indeed, such variance of expertise could dramatically impact on how the patient is assessed leading to different care pathways for treatment and rehabilitation. To overcome those shortcomings and to standardize approaches, pen and paper-based approaches were introduced, for example, Berg Balance [106]. The rationale being that a specific set of guidelines could direct all healthcare professionals in a structured and methodologically robust manner to ensure patients could be routinely and appropriately screened/ assessed during specific tasks under observation. This ensured a more harmonized approach to patient assessment and meant that data acquired from pen and paper assessments could be compared/contrasted within and amongst different patient groups. Moreover, it allowed greater insight to pathological subtypes by providing greater granularity of investigations, with the application of thresholds to determine if a person aligned to a particular condition (or not) or how severe they rated, for example, loss of physical or mental functionality.

The advent of standardised pen and paper approaches to the assessment process ushered in a new wave of cooperation and innovation in medicine. Their formation required groups of individuals or teams to formulate collaborations, ensuring the proposed pen and paper guidelines for a particular assessment were well informed. Failure to agree a collective professional accreditation may have resulted in rejection of the proposed pen and paper method. Moreover, it ensured appropriate scientific rigor was applied for valid and reliable scoring criteria within assessment guidelines. However, limitations are also found within pen and paper-based approaches to patient assessment. Inter-rater reliability is a problem when it comes to how different healthcare professionals or researchers may use pen and paper assessments, for example, Unified Parkinson's Disease Rating Scale motor exam [107]. Despite best efforts to harmonize areas of assessment, assessors still use their own (and perhaps biased) subjective opinion to score those being examined. Again, this can lead to large discrepancies and result in the pen and paper approach being described as a blunt tool, good but not good enough. Moreover, data acquired is limited as it is usually based on a Likert scale (e.g., 0-5, or 0-10 score), which can only

be analysed within the confines of its intended outcome (more on this later), which can lead to floor or ceiling effects of scores. This has implications when trying to detect subtle pathological changes, which may be at the very early stages of disease onset. Thus, the need for more accurate and higher resolution approaches to patient assessment became evident.

The story and scale of digital technologies in healthcare goes far beyond the scope of this chapter and book, but what is widely known is how the influence of digital approaches have revolutionised medicine in the 20th century and beyond. Use of digital technologies and instrumented approaches to acute clinical care range from the development of vital signs monitors (e.g., heart rate, oxygen saturation) through to magnetic resonance imaging to create pictures of the anatomy and the physiological processes of the body. Yet, these are expensive and large pieces of equipment, which require specific expertise for appropriate use and data interpretation. The rise and proliferation of integrated microelectromechanical (iMEMS) systems means technology has dramatically reduced in size to enable use beyond bespoke facilities to routine/community/low-resource settings. Such systems paved the way for digital technologies to be worn on the person for prolonged periods and during common ADL. The most evident/common being the 24-hour Holter monitor, an ambulatory electrocardiography device. This example allows the patient to wear (relatively discreetly) a clinically useful device during habitual activities, affording healthcare professionals a more representative method to assess cardiac rhythm during ADL. Thus, use of a wearable digital technology device can provide real-world data to better inform patient treatment and management.

3.2.1 *Wearables*

Wearable technologies are multifaceted, they come in many shapes and sizes with a plethora of functionality depending on embedded sensors and/or proprietary software used to interpret raw data [34]. By far the most common type of digital-based wearables are activity monitors that usually have additional sensing capabilities such as heart rate and geo- graphical positioning i.e., global positioning systems (GPS). These devices are predominantly commercial and aimed at the health and fitness market. Others are for bespoke research devices, which may provide a greater granularity of data to tease out any minute changes in behavioural activity in response to an intervention. Generally, the greater the sensing capability of the wearable the greater the cost due to additional electronic components and complexity of data interpretation. This is particularly evident with inertial sensor-based wearables to detect activity and other specific aspects of physical functioning.

3.2.1.1 *Inertial and magnetic sensors*

The most common type of inertial sensor is the accelerometer, a device that measures applied acceleration (meters per second squared, m/s^2) acting along a sensitive axis. When attached to an anatomical segment (e.g., leg, arm) they can be used to measure the rate and intensity of movement in up to three axes/planes. These are termed tri-axial devices measuring in the anterior-posterior, medio-lateral and vertical planes, which can provide comprehensive and extremely insightful data regarding quantity and quality of movement. Accelerometers respond to both the frequency and intensity of movement making them superior to actometers or pedometers, which are attenuated by impact or tilt [108]. Accelerometers have made activity wearables popular due to their ability to gather useful data at various sampling resolutions and relatively low current draw (0.180.7 mA). Indeed, their low current draw means that they can be deployed (with small batteries) for prolonged periods of many days, weeks or even months. When integrated with a real-time clock they also help differentiate activity patterns over extended recording periods. They are also highly configurable whereby their bandwidth can be set through coupling filter capacitors, and they have high resolution at typical sampling frequencies used for the detection of walking (2 mg at 60 Hz). Evidence of their use to assess walking/gait is proliferate within the literature where examples include their use to assess those with neurological disorders in controlled and habitual environments.

While use of accelerometers has been beneficial and insightful to better understand, for example, walking, their sole use remains curtailed to a limited set of movement characteristics. Expanding sensing capabilities to include other inertial sensors during supervised and habitual testing follows the current trend to determine a more rounded picture of the patient's physical functions. Incorporating gyroscopes (angular velocity in degrees per second, /s) or magnetometers (detecting and measuring magnetic fields, Gauss, G) facilitates a much greater opportunity to gather a complete representation of the wearer's movements but comes with a memory, battery, and data handling trade-off. Typically, the greater the sensing requirements the more data that is gathered which quickly consumes memory storage and battery resources. However, it must be noted (not including the technical expertise of the research team), that the addition of these extra sensing modalities will depend on the aims of a research project, as it may be sufficient to use an accelerometer only. Yet, incorporating gyroscope and/or magnetometer sensors with accelerometers can provide a wealth of kinematic data but with notable challenges in deriving outcomes of interest that are sensitive to a research hypothesis. What kind of data can be acquired with such sensors? Accelerometers have typically been used to quantify postures due to orientation of the wearable at wear location, physical activity due to intensity of the signal generated, and step detection. Gyroscopes have also been used for step detection but more readily for turning characteristics. Magnetometers are perhaps less readily evident in the literature for generic movement analysis but have been found in more complex approaches to determine where a body is in space and how one body segment moves relative to another [109]. A combination of tri-axial magneto and inertial (accelerometer and gyroscope) sensors results in a wearable which is classed as a measurement unit with 9-degrees of freedom. That configuration of sensors is adopted with sensor fusion algorithms when estimation of the pose/posture in the 3D space is required by combining the good dynamic response of the gyroscope, with the drift-free inclination and heading estimates provided by the accelerometers and magnetometers in static conditions [110]. Such analysis for each or a combination of inertial sensors is complex and important to consider at the outset of data capture. Thus, before use of an inertial or magnetic sensing approach to activity or fine motor assessment it is important to take time to consider how data should be processed and analysed to generate outcomes that are sensitive to the specific research aims [110]. The first technical/engineering step will usually be to consider the features to be extracted from the high-resolution raw data. The latter specifically refers to the unprocessed data created by the sensor(s) and gathered by the hardware components of the wearable.

3.2.1.2 Feature extraction

From an engineers or data scientist's perspective, inertial and magnetic sensors are fascinating devices to work with due to their multiple pragmatic sensing capabilities by offering high resolution data that can be analysed in time, frequency, and multiresolution domains. This is of paramount interest in the healthcare sector as it seeks low-cost, scalable solutions that are sensitive to the individual for personalized approaches to diagnosis and treatment. Due to their miniature size, inertial and magnetic-based wearables can be attached at any anatomical location (e.g., feet, legs, waist, wrists, chest, arms, wrists, and head). Obviously, the long-term use of any device at those locations will depend on the form factor and how aesthetically pleasing (i.e., fashionable) they are. However, the devices may not "catch on" to become fashionable if they provide no meaningful information based on the application/purpose they are designed to measure. Specifically, no matter how cool/fashionable the wearable looks, if it cannot provide robust and accurate data to quantify a specific activity/task it is a risk when worn. Notable examples here include wrist worn step counters that can be manipulated by swinging one's arm even while in a seated/sedentary posture. So how does an engineer ensure the outcome(s) to be measured is/are valid and reliable? The first objective is to define appropriate characteristics/features from the sensors signal(s), which are used to inform how subsequent algorithms interpret wearable data to produce the desired outcome(s). This process may be termed feature extraction and plays a key role in the utility and accuracy of wearables. One point to note is that wearable attachment location plays a key role in the decision-making process of how the wearable is designed and how its data is analysed. For example, an accelerometer-based wearable worn on the lower leg will generate vastly different data

to the same wearable worn on the lower back (Figure 4). Thus, interpretation of the data (and the algorithm used) will vary greatly with numerous analytical challenges associated with each wear location. How one decides to interpret the data to inform the algorithm is the key.

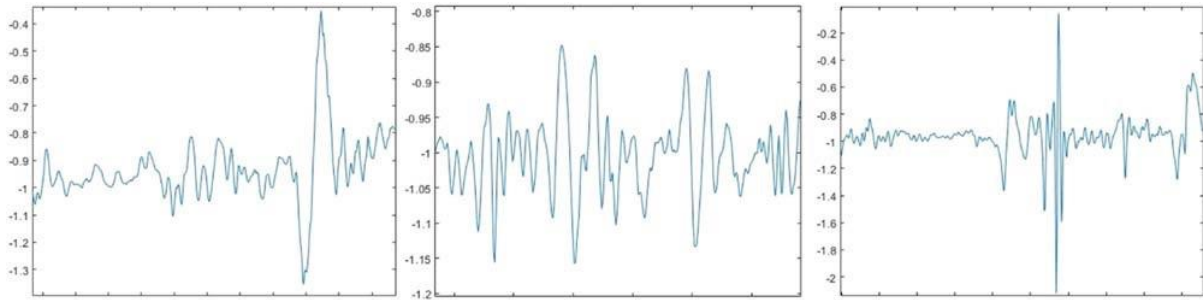


Figure 4. From left to right various acceleration signals during the same task from an accelerometer-based wearable worn on the right wrist, lower back, and right leg.

3.2.2 Preparation is key

3.2.2.1 Preliminary wearable configuration

The focus here won't be a comprehensive guide to describe how the sensors board is configured in hardware as currently there are many commercial options for researchers to acquire technology that enables them to jump right to data capture, without having to worry about sourcing sensors and associated components. However, it is worth mentioning here briefly to raise awareness that the sensing capabilities of inertial and magnetic-based wearables are preconfigured at manufacture due to applied functionality and the peripheral components associated with each. Firstly, a magneto-inertial sensor may be considered according to different sensing grades or ranges. For example, most wearable accelerometers range from 2 to 16 g, the former useful to examine discrete and low intensity movement (e.g., postures) while the latter would be useful for high impact and intensive actions (e.g., fall). Examining wearable raw data at the time of a fall event captured with a minimal range accelerometer (2 g) would see something similar to Figure 4, where a portion of data appears missing. This is often referred to as clipping (Figure 5) and is sometimes the first pragmatic problem encountered when dealing with free-living data (due to the many unknown activities performed by the individual) and choice of wearable device. Secondly, filter capacitors are chosen to configure the hardware at a predefined bandwidth, which is usually -3 decibels (dB, or mathematically: $\sqrt{2}/2$), where that value is often known as the half power point and is useful to cut-off half the power at that frequency. This is important when considering what movement to measure as choice of filtering capacitor will attenuate some signals to ensure the wearable measures what a manufacturer specifies it should, that is, whether its fit-for-purpose. Both are important considerations when deciding what to measure and how to measure it.

3.2.2.2 Configuring for data capture

Depending on how the wearable is configured, magneto-inertial sensor data generates a few to many hundred samples (data points) per second. This corresponds to the sampling frequency (f_s) of the device and will ultimately depend on the outcome(s) of interest. For example, measuring broad trends of physical activity for a device worn on the hip may require a low f_s (e.g., 5-10 Hz) only as the wearer is highly unlikely to perform different categories of physical activity tasks beyond the minimal time period of data capture, that is, 0.1 second (where 10 Hz captures data every 0.1 second as defined by Equation 1). Typically, general trends/behaviours of physical activity (for all ages) are investigated over many minutes, hours, or days so a low f_s will provide enough resolution to ensure data capture to best represent how the wearer moves.

$$\text{Time} = 1/\text{Sampling frequency}$$

(Equation 1)

Alternatively, investigations examining discrete or highly subtle features of movement, such as sequences of the gait cycle, hand tremor or transitional changes in posture will require much higher f_s to ensure the wearable captures enough data during the period of measurement to adequately and accurately understand how the movement was performed.

Typically, gait events occur in the 0.6-5.0 Hz range and so the correct type of wearable must be chosen or configured to ensure optimal data capture for events in that range [111]. This isn't something to be chosen likely as this conforms to a certain set of signal processing-based sampling criteria defined by the electronic engineer Harry Nyquist (1889-1976) who lent his name to important frequency and rate parameters that define the basic properties of magneto-inertial wearables. The Nyquist rate is of utmost interest here as the chosen f_s (i.e., the discrete sequence of samples) must adequately capture all the information from a continuous-time signal within a finite frequency range (i.e., bandwidth). Pragmatically, the optimal rate can be set at twice the bandwidth and so for a movement like gait this could equal 10 Hz.



Figure 5. Tri-axial accelerometer signals with grey trace/signal clipped (green circle) and so hasn't adequately captured (gait) task

That may be optimal for examining general trends in gait patterns (walking/ambulatory activity) and has been used successfully in a commercial device often seen within the literature to examine ageing and pathological differences between different populations [112]. Although sufficient to examine general, high-level patterns of physical activities, the same device could not be used to examine discrete components of fine motor movement but again, choice of device/configuration is dependent on determining what outcome may be useful within the research aims. Alternative devices for capturing high resolution/frequency type data exist that can be worn on various anatomical locations, depending on manufacturer's recommendations. Typically, and briefly, these can be configured with proprietary software to set the f_s up to 100 Hz or more. Although there are other considerations to consider such as oversampling and filtering, they have been extensively detailed elsewhere and the technically orientated reader is directed there for further reading. Mainly, the trend for wearables focusing on human movement analysis have aligned to use a f_s of 100 Hz to account for any anomaly such as slips trips or falls which may be useful to capture as gait analysis encapsulates fall prediction as well as understanding the influence environment. Where digital filtering is to be used to process raw data, low-pass or band pass filters are generally the preferred options, which have adjustable parameters called cut-off frequencies (f_c), attenuating unwanted signals above or below those values. Use of digital filters

help “clean and smooth” the signal by removing, for example, high frequency components such as electrical interference or low frequency components such as drift.

3.2.2.3 Examining the signal

Key to any analysis with wearables is the examination of all raw data, where possible. Most commercial wearables may not facilitate examination of these data for two basic reasons. First, many wearables have raw (acceleration) data immediately processed into an output of some description, resulting in a time series of much lower frequency, such as one data point for every 60 seconds. In that scenario, raw data is never accessible to the manufacturer or any user, as it is never written to memory. Secondly, wearable data may be commercially sensitive for the manufacture. Where raw, unprocessed data is available it is important that it is examined to ensure it “makes sense.” While looking and understanding signal traces such as those in Figure 5 may not be for everybody, they help understand the obvious: when the device was set to record and was attached to the wearer while he/she was moving, something caused the lines/signals to deviate about the horizontal. Ergo, it appears that the wearable managed to capture the movement of interest. Conversely, if the wearable didn’t work as expected but still captured data, one might expect to see the dreaded flat lines which would resemble if the device was recording data while lying motionless on a table. (This simple hack/check is useful to examine if a wearer wore the wearable or not during longitudinal testing over many hours or days.)

3.2.2.4 Basic approaches

Knowing what to extract from inertial signals and determining how useful they are is an ongoing area of research which is sensitive to, for example, where the device is worn and whom it is worn by such as a specific patient population, and what might be insightful for those with stroke may not be for those with Parkinson’s disease. While the field of feature extraction is complex, here I will present basic concepts defined on what can be measured that may be useful for those first-time researchers in the field.

As previously alluded to physical activity and/or general trends in human activity behaviour (such as sedentary periods and ambulation, that is, periods of sitting/lying and walking, respectively) require examination of the magneto- inertial signal(s) over many samples/seconds. So how does one go from raw data to meaningful outcomes such as time spent in moderate to intensive physical activity or time spent walking? Translation is achieved by applying mathematical formulae to the processed/filtered signal. In the early days of utilizing magneto-inertial sensors some basic methods were used in combination with thresholds such as examining the mean (\bar{x}) and standard deviation (σ) of data samples for static postures and dynamic or static activity, respectively [113,114]. But how long should those samples be? Deciding how long those samples should be is a key question which will impact the accuracy of activities detected but will come with a computation trade-off for the device (if used in-situ) or computer (post-processing offline): the greater the number of samples chosen the quicker the computation but the blunter the analysis. Additionally, choosing too many samples will exclude discrete periods of interest such as a physical activity performed in a very short time period. For physical activity the sample size is typically described as an epoch or activity counts of 30 or 60seconds duration and is chosen when the wearable is programmed. Raw physical activity data may look like that in Figure 4 but is more often presented as summated counts/epoch (Figure 6). Once thresholds are applied one can examine common outcomes such as times spent in sedentary, light, moderate, and vigorous activities (Figure 6). Thresholds for the purposes of physical activity analysis are the subject of ongoing research to find optimal values for various cohorts examining different health related topics. In short, use of simple mathematical operands and application of thresholds are a very useful and perhaps first approach to extract features and determine meaning from wearable outcomes.

For other devices, such as those aiming to quantify walking, it would be inappropriate to group predefined samples together as data captured during that task may span several epochs of data and subsequently be incorrectly considered in isolation rather than collectively. Instead, more intuitive

approaches must be taken. Accelerometer data captured at 10 Hz from a uni-axial worn on the upper leg is presented in Figure 6. Here there are three different scenarios based on how the signal could be interpreted based on the application of different static (fixed and hard coded, e.g., 125) and dynamic (based on σ of the signal) thresholds to extract features of the signal. The features of interest here (based on where the wearable is worn and how walking and steps are detected) relies on the identification of the trough (or red negative peak) in the first instance (*Top*). A more intuitive approach considers the (positive green) peak immediately before accounting for the natural swing of the leg during walking, to better define an actual stepping event, or series of events (*Middle*). Those methods rely on the correct definition of thresholds to the positive and negative axes of the accelerometer data which when used in tandem with a peak detection methodology will either include or exclude peaks and ergo, detection of walking and steps [115]. A pragmatic example of how predefined thresholds can negatively impact accuracy of instrumented walking and step detection is often found when applying wearables, which may have been designed for use of young healthy adults, on older adults with reduced clarity of walking. The latter's inability to walk purposefully to generate the clean signals as depicted in Figure 4, will mean that signals produced will not exceed any fixed threshold. Static thresholds may be defined by examining the \bar{x} of signals gathered on a group of younger adults during pilot testing to best gauge how to examine all signals for peak detection. Alternatively, the wearable could adopt a flexible/adaptable threshold approach (Figure 4, bottom) by utilizing σ of a wearable signal which could enable a personalized threshold for the wearer, adapting to how slow or fast they could walk.

3.2.2.5 Advanced approaches

A more computationally intensive but higher analytical resolution technique called a sliding window may be used to better interpret wearable data compared to examining predefined block/epochs. As the name suggests, this approach slides a predefined window along the data to estimate \bar{x} and σ or other features (within that window) to better understand the fluctuations in inertial data on a second-by-second basis, rather than at millisecond resolution. Although the window is predefined, it is a continuous process of signal evaluation where the current window of interests overlaps with the previous and so on as it progresses along the entire signal. The greater the overlap the more detailed the analysis but higher the computational trade-off.

Although \bar{x} and σ have been presented here in the first instance, the extent of mathematical permutations that could be used to examine a portion or a complete signal are quite extensive. Table 1 presents an example of an array of features that could find utility when examining movement from wearable data. Previously they were used to investigate postural control during standing balance tests in those with Parkinson's disease [116]. Although Table 1 is by no means a comprehensive list, it represents many features used to investigate various movement tasks. The referenced study generated 175 outcomes based on features listed in Table 1 due to the bi-axial approach used. Although the study later investigated some machine learning approaches to find the optimal outcomes for their study cohort, it showcases the extent to which inertial data can be investigated to extract features of interest within their signals. Although the study examined outcomes on the entirety of 30 seconds standing balance signals, the feature selection investigation could be taken further. By investigating how those outcomes fluctuate based on iterative periods within the standing balance test, one can investigate how postural control fluctuates during a more prolonged (120 seconds) test [117].

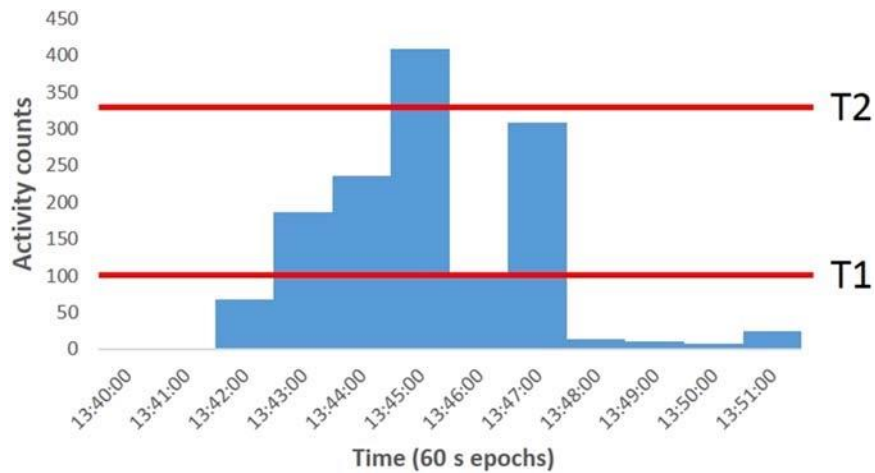


Figure 6. Physical activity count data subjected to threshold's 1 and 2 (T1 and T2). No data (13:40 to 13:41) equals sedentary, >0 and $<T1$ = light, $>T1$ and $<T2$ = moderate and $>T2$ = vigorous.

As described the study used to generate the array of features in Table 1 later used and contrasted machine learning approaches to find the optimal features to examine postural control in older adults with Parkinson's disease [116]. Often, machine learning is touted as the next great innovation step to better understand wearable applications, particularly in healthcare. That may be true, as there is no doubt about the power of machine learning to analyse big wearable data. Yet, the power of machine learning will only be as good as the features used to train and develop it so the processes and approaches described here are of paramount importance to the development of the field.

Beyond the use of time and frequency-based features, another approach involves the use of multiresolution analysis. It has been argued that this approach, which can be loosely described as a time-frequency analysis, is more suited for non-stationary signals such as those encountered in human motion, where traditional Fourier transforms fall short. Specifically, Fourier transforms are used for providing a description of the overall regularity of a signal and are not suited to characterize the temporal distribution of singularities and transient events [118]. As its name suggests, multiresolution analysis analyses the signal at different frequencies with different resolutions. It is designed to give good time resolution and poor frequency resolution at high frequencies but good frequency resolution and poor time resolution at low frequencies. Though the full description and explanation of multiresolution approaches are beyond this chapter, I draw the reader's attention to one multiresolution approach, the discrete wavelet transform (DWT, which could be likened to filtering depending on approach taken). In short, the DWT involves splitting the signal into high scale (low frequency) components called the approximation and low scale (high frequency) components called the detail. A further reconstruction process is then necessary in order to have the same number of samples as the original acceleration signal and is useful to examine nonperiodic and fast transient features, that is, high frequency for short durations, of movement signals [119]. The latter used this to good effect to extract features akin to localized time and frequency data to examine movement characteristics for different patient subtypes. In the next section of this chapter, I will examine further feature extraction techniques for specific functional tasks such as balance and gait. The methods included will be founded in supervised, clinical testing but with supporting exploration of those techniques to instrument tasks during free-living, unsupervised monitoring.

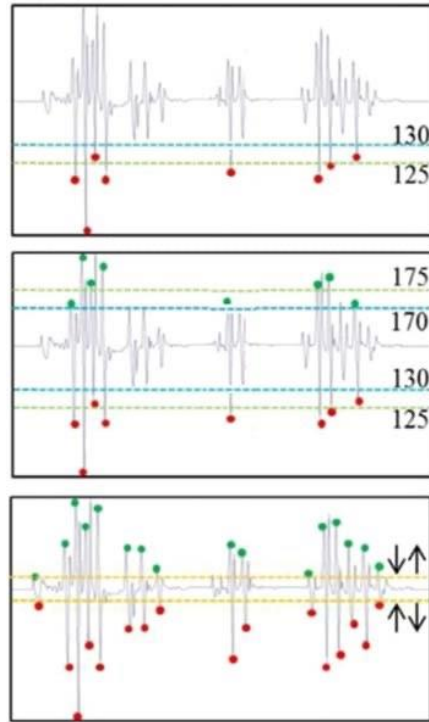


Figure 7. Uni-axial accelerometer data from a thigh worn wearable. Top: different static thresholds applied to negative axis (eight steps, red dots/troughs) with some troughs missed. Middle: Static thresholds to positive and negative axes (eight steps, combination of green peaks with red troughs), some troughs missed. Bottom: Dynamic thresholds (based on σ) to account for differences between individuals, more troughs included (16 steps).

Table 2. A toolbox of time and frequency-based feature extraction options to investigate raw data, adapted from [120]

Domain	Domain- Measure, description and unit
Frequency	Power HF—Fraction of power of the signal for high frequencies (4-7 Hz)—%
Frequency	Peak HF—Frequency of the maximum of the power spectral density (PSD) for high frequencies (> 4 Hz)—Hz
Frequency	RHL—Power ratio of the high (3.5- 15 Hz) to low (0.15-3.5 Hz) frequency components—unit less
Frequency	F50—50% power frequency: frequency containing 50% of the total power—Hz
Frequency	F95—95% power frequency: frequency containing 50% of the total power—Hz
Frequency	CF—Centroidal frequency, the frequency at which spectral mass is concentrated—Hz
Frequency	FD—Frequency dispersion, a measure of the variability of the PSD frequency content (zero for pure sinusoid, increases with spectral bandwidth to one) —unit less
Frequency	Entropy—Power spectrum entropy of acceleration—unit less
Time	Jl—Jerk Index, a function of the time derivative of the acceleration, which is commonly viewed as an index of smoothness— mm^2/s^5
Time	NJI—Normalized Jl, normalized by dividing it by SP^2-1/s^5
Time	MD—Mean distance from center of Center of Mass (CoM) trajectory—mm
Time	RMS—Root mean square, distance from center of CoM trajectory—mm
Time	SP—Sway path, total CoM trajectory length—mm
Time	MV—Mean velocity of the CoM, computed as the median value of the absolute value of the time series obtained through the derivative of the displacement—mm/s
Time	SA—Sway area, area included in CoM displacement per unit of time— mm^2/s
Time	CEA—Confidence ellipse area, area of 95% confidence ellipse— mm^2
Time	mSCEA—Minor semi-axis of CEA—mm
Time	MSCEA—Major semi axis of CEA—mm
Time	$ \text{90-Mdir} $ —Angular deviation from anterior-posterior sway of the maximum variance direction—degrees ()

3.2.3 Instrumenting motor tasks

As described magneto-inertial wearables can be attached to various anatomical locations to quantify a range of different movements, where physical activity is the most common with devices typically attached to the wrist. Here, I focus on specific motor aspects of human movement and how they have traditionally been assessed within a closed/supervised environment. I examine how those traditional approaches to motor assessment have now been instrumented with magneto-inertial wearables, for more in depth and objective assessment. Some data is presented along with methodologies to instrument specific movement characteristics. Here, I focus on gait instrumentation only. Although many components of human movement can be quantified by wearables, mTBI gait is a novel proposal of this thesis whereas another motor task (turning) has been previously examined [86]. (The online published version of this chapter details additional instrumented tasks e.g., postural transitions.)

3.2.3.1 Posture

After the suggested use of magneto-inertial-based wearables to capture static and dynamic time series data when attached to various anatomical segments [114], postural assessment is perhaps the next obvious step in instrumenting human-based functional tasks. Therefore, we know accelerometers are sensitive to movement, but one should also be aware that they are also sensitive to the acceleration acting on a stationary object, which is equal to about one time the force of gravity (1 g or $\sim 9.8\text{ m/s}^2$) in the upwards direction (from the ground). If a wearable has tri-axial sensing capabilities one can examine the effect of gravity on each axis of the accelerometer as it changes orientation, to infer how a person adapts and changes their posture. No force on the sensitive axis generates an acceleration of 0 g (0 m/s^2) but if the wearable is rotated through 90° , static acceleration approaches $\pm 1\text{ g}$. Later work investigated the orientation of accelerometers when attached to the person, chest and upper thighs for whole body assessment, to understand how they were lying (chest and legs both 0g), sitting (-1g chest, 0g leg) and standing (chest and legs both -1g) [113]. Subsequently, the same authors examine various thresholds applied to the time series accelerometer data when the wearer was at rest (static) for a tailored assessment of the individual's posture in clinical settings [121]. When assessed over many hours or days, one can then build a picture to better understand the sedentary behaviours of individuals with reduced mobility. Such an approach showed pragmatic utility for objective patient management to prevent pressure sores [122].

Clinical assessment of balance is often used to understand postural control of an individual, which if poor may allude to an underlying vestibular and/or neurological health condition. One of the early investigations showed the robustness of using wearable sensors for balance assessment compared to higher cost, fixed location laboratory-based equipment (e.g., force plates) [123]. Stratified work in the field to harmonize how postural control could/should be assessed with a wearable across the ageing spectrum was later developed and disseminated by the National Institutes of Health (NIH) Toolbox initiative [124]. Specifically, recommendations point to use of an accelerometer-based wearable on the lower back to capture insight and objective high-resolution data from a test where it appears nothing may be happening [125,126]. What I mean is that for most participants who perform a balance test their vestibular system will keep them rigid, but for those with a postural control impairment, then very subtle changes in how one keeps themselves rigid and balanced will be detected by the wearable which may go unnoticed by the assessor's eye. Of course, there are many variations in how the standing balance test is performed (e.g., feet together/apart/tandem, eyes open/closed, stand on ground/foam) to stress test the participants system and use of an accelerometer to instrument the process provides a wealth of information.

Many of the features investigated for instrumented postural control are represented in Table 1. Studies have utilized those features and some others to test them in various populations to assess their reliability and validity in different technologies [127] as well as their ability to discriminate between different cohorts [117,128,129]. More longitudinally they have also been investigated to examine the

relationship to cognitive impairment and motor scores in those with Parkinson's disease [130]. As a result, we can see the use of inertial wearables to instrument a simple test like standing balance to provide many more options to assess an individual, compared to simple observation and trying to determine how good their postural control is. By understanding the fundamentals of how the inertial sensing technology works from basic postural tasks I can springboard to instrument a dynamic task i.e., gait.

3.2.3.2 Gait

Interest in instrumented gait assessment has risen sharply in recent years due to the aligning of multidisciplinary teams. More translational research is now evident between engineers, computer and clinical scientists. The latter needing better approaches to assess their patients, the former willing and able to provide more sophisticated technology to do so. But why gait specifically? Laboratory-based work using instrumented walkways has shown evidence to suggest that gait can be a useful prognostic and diagnostic (surrogate or bio) marker [131]. This has implications for how people may be diagnosed and treated as use of a simple walking test could provide pragmatic and more importantly, low-cost approaches to improve care. Yet, instrumented walkways are expensive and bulky but more importantly they only capture a limited proportion (i.e., snapshot) of a gait test in a closed/supervised environment, where the latter is known to influence habitual walking performance [85,132]. Thus, use of wearables became quite apparent as suitable tools to capture prolonged periods of gait in more natural settings. It is hypothesized that application of wearables on the person in their usual surroundings of their home and community would paint a better picture of how they walk on a day-to-day basis compared to the optimal testing conditions within a clinic, that is, no clutter, level ground, good lighting, etc.

Research in this area is awash with many studies and reviews of how to capture gait and theoretical models associated with different gait parameters, here are a few [133–136]. Here, I will provide a brief summary of how the field has evolved through the use of inertial wearables to capture gait beyond the clinic. Given the increased interest in gait analysis, many algorithms and approaches have been proposed on how to best capture it. These range from tri-axial accelerometer to tri-axial gyroscope or combinations worn either on the feet, lower legs or somewhere around the waist area. As previously mentioned, multiple wearable attachment beyond the clinic is not very practical so generally the field has aligned to use of a single wearable worn on the lower back, predominately on the fifth lumbar vertebrae (L5). Why here? It is quite a discrete location as many current devices can be worn directly on the skin under clothing for many days. True, current devices may be 4-5 mm thick but as previously detailed current studies report no issues with patient compliance [137]. More importantly it ties in with the biomechanical quirk detailed in the previous section close to the CoM. Zijlstra and Hoff put this to good use in 1997 by modelling the CoM trajectory during gait which was used to predict amplitude and timing of pelvic displacement [138]. By considering the biomechanical sequence of the pelvis as it travels through space during gait, the authors utilized the now famous (to those in the field) inverted pendulum model (where it is assumed the body rotates over the foot in contact with the ground [139] to infer that stride length influences amplitude of pelvic displacement in the vertical direction. Later, Zijlstra and Hoff derived a more user friendly approach (Equation 5) to show the relationship between CoM and stride length through use of known variables: llength of pendulum (i.e., measured height of wearable from the ground as the wearer is in a standing posture); hchange in height of CoM, estimated by double integration of a_y and controlling for drift by using a high pass fourth-order, zero-lag Butterworth filter [140]. This approach has proven very useful to determine estimates or proxy values for step length as quantifying spatial gait values from a wearable is fraught with limitations such as requiring and assuming the wearer is walking at normal gait speed in a linear direction [140]. Yet, the method remains popular, especially for use in controlled/laboratory settings where the assessor can dictate how the wearer walks. Moreover, other methods used by Zijlstra and Hoff [138,140] proved insightful as to how different characteristics and features of the gait cycle could be extracted from

interpretation of inertial signals. For example, they implemented a zero-crossing study of the displacement in the anterior-posterior direction to examine left to right stepping.

$$\text{step length} = 2\sqrt{alh - h^2} \quad (\text{Equation 5})$$

If not familiar with the area, one may now be wondering, what are all the different characteristics of the gait and how many are there in addition to determining left and right steps as well as step length? If one enters “gait cycle” into a web browser and searches images, a plethora of images focusing on such terminology as cycle double support time, mid-stance, terminal swing, etc. In short there are two key components that need to be examined and quantified separately for each foot to provide a stepping to stone to the terms: Initial contact (IC, when the heel first touches the ground) and final contact (FC, when the toe leaves the ground to begin the swing forward journey to the next IC). Thus, IC and FC detection within the signal of an inertial wearable have become the focus for many features extraction approaches. Popular methods to define characteristics of the gait cycle including but not limited to IC and FC based on different features extracted from an inertial wearable located on the waist includes:

1. IC timings of the peaks of the low-pass filtered anterior-posterior acceleration preceding the positive-to-negative transitions (i.e., zero-crossing) of the filtered anterior-posterior acceleration [140,141].
2. Searching for IC in a region of interest defined by the positive values of the filtered anterior-posterior acceleration. In that interval, local maxima of the raw acceleration are searched where the timing of one of the maxima is identified as IC. To select the correct local maximum, several empirical rules are applied. Once the IC is identified, the timing of the first local minimum occurring after the IC is identified as FC [142].
3. The values of the acceleration norm falling within a sliding window of fixed length are summed (sliding window summation). The difference of the resulting summation values and those obtained from the window length samples are then computed to remove gravity. The resulting pattern is a smooth curve periodically crossing zero. The instances of negative-to-positive transitions are then used as markers to determine the step duration. FC timings are not estimated [143].
4. Gait events are searched within regions of interest identified from a multiresolution approach, that is, the signal reconstructed with the first three levels of detail of a stationary wavelet decomposition of the vertical acceleration. Those featuring the highest peaks of the vertical acceleration (i.e., containing the instrumented side IC) are only considered. The ipsilateral IC and contralateral FC were determined from the vertical acceleration in the region of interest, then the ipsilateral FC was identified from the anterior-posterior acceleration. The contralateral IC was identified from the medio-lateral acceleration [144].
5. IC timings are identified as the times of the minima of the signal obtained after applying a multiresolution approach (Gaussian continuous wavelet transformation) to the vertical acceleration recorded. The resulting signal is then differentiated, and FC timings are identified as the instances of its maxima [145]. Additionally, the accelerometer approach used here was supplement with a gyroscope to define right and left IC/FC’s (steps).

Method number 5 has been used extensively in the literature given its apparent robust use in and beyond the clinic and will therefore form the methods used in later chapters [146]. A step-by-step is also provided including pseudo code on how it can be implemented in MATLAB[®] with tri-axial data in.csv format is also provided [147]. Figure 8 graphically represents how the IC/FC events are extracted from the method 5 in conjunction with adopting the step length methodology to estimate many gait

characteristics: step length, step time, swing time, stance time and step velocity (a proxy for gait speed). However, although one wearable may be easier to configure, wear and synthesis arising data when highly impaired gait is analysed (e.g., those with advanced Parkinson’s disease), methods employing one inertial unit on each leg is preferred for more accurate detection of ICs and FCs [148]. It has been shown that in similar pathological cohorts when exploiting some lower limb invariant kinematic characteristics, both missed and extra events can be avoided and that the errors can be reduced to 1% for the stride duration, 2%-3% for the step and stance durations and 6% - 7% for the swing if multiple sensors are used [149].

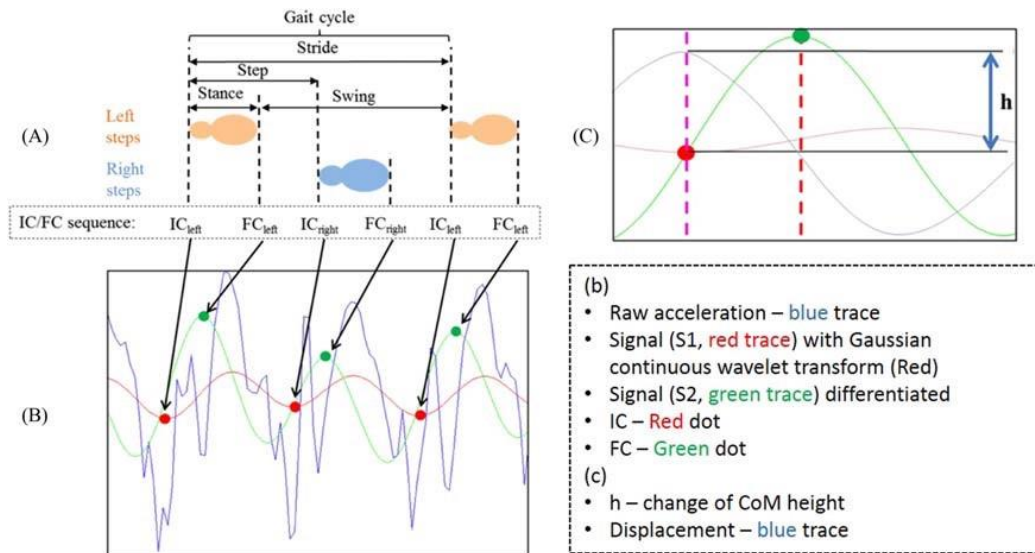


Figure 8. Estimating many gait characteristics (A) from IC and FC events (B, b) in the raw accelerometer signal/data along with change in Center of Mass (C, c) height (h).

Once those gait characteristics have been estimated they can be investigated further, such as the variability (e.g., standard deviation of step time) or asymmetry (timing differences between left and right) of steps, which has informed the development of conceptual gait models [150]. Gait characteristics defined here have been described by the referenced theoretical approach as micro, which form a focused examination of the subtle (millisecond) changes of inertial data within the macro behavioural changes of the longitudinal (hours/days) inertial data. Others have defined quality and quantity models through use of frequency-based characteristics [151,152]. However, when considering a macro/micro or quantity/quality approach beyond the clinic one must first identify when the wearer is performing a gait task. To achieve this, heuristics have been employed to define when the wearer is upright (wearable attached to lower back in a predefined orientation, x acceleration) and moving (dynamic, σ acceleration). Once periods of possible gait events are detected, an IC/FC methodology (e.g., 1 to 5 described here) can be applied to that section of inertial data to examine the gait cycle [153]. These approaches for gait assessment in the clinic and beyond are the source of ongoing research and constitute considerable efforts to utilize gait as a low-cost and pragmatic tool for remote patient assessment [154].

3.3 Conclusion

This chapter investigated the current state of the art for instrumented motor assessment with inertial wearables. Use of discrete and affordable/low-cost inertial sensors have paved the way for them to be investigated within wearables as useful clinical tools, to aid assessment of individuals with motor impairments. To date, many traditional physical motor assessments have been instrumented by attaching inertial-based wearables at different anatomical locations, capturing raw acceleration and angular velocity data. Examination of the raw data and deriving useful features from the signals have provided informative spatial, temporal, and frequency-based digital outcomes. Although clinical assessment under observation is still the preferred method to determine e.g., mobility limitations, use of these wearables and their digital biomarkers/outcomes could provide objective and personalized high-resolution data that can augment clinical decisions. Yet, although the use of wearables and digital outcomes is new, the field is quickly evolving.

To this point, I have detailed some current mTBI management challenges (chapter 1) and explored my hypothesis, use of digital approaches to better manage mTBI (chapter 2). Subsequently, I focused attention on one mode of digital technology and its use on instrumenting gait to later inform mTBI-based motor assessment in this thesis. Here, the focus was on gait assessment alone as that has not been fully explored within mTBI (the latter alludes to use during free-living and as a mechanism to examiner rehabilitation due to intervention). Next, I reconnect to the findings from chapters 1 and 2 by investigating PoI1 and PoI2 and exploration low-cost inertial-wearable technology for supervised gait assessment in a low-resource setting.

Chapter 4: Exploring the validity and suitability of a low-cost wearable for motor assessment in a low-resource environment

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The journal article “*Investigating the AX6 inertial-based wearable for instrumented physical capability assessment of young adults in young adults in low resource settings*” was published in **Smart Health** in 2021 (URL: <https://doi.org/10.1016/j.smhl.2021.100220>)

4.1 Introduction

Chapter 3 detailed how inertial-based technology can instrument one of the components within mTBI motor assessment i.e., gait. The latter is highlighted within this thesis as it remains under explored within mTBI and may have pragmatic utility to inform RTP as well as effectiveness of intervention (highlighted in chapter 2). In this chapter, I explore acceptance/useability, validity and capability of a low-cost approach in instrumented gait assessment and its ability to discriminate those with recent SRC history versus those without. Work undertaken here will help shed light on PoIs 1-2.

4.2 Background

Wearable-based IMU's have become popular for instrumentation of motor tasks (chapters 2 and 3), due to attachment at any anatomical location without burden and provision of raw (sample level) data. Chapter 3 focused on gait and detailed the fundamental techniques/skills to convert the raw inertial data to quantifiable outcomes e.g., step time. Currently, there are a plethora of inertial-based wearables that enable gait instrumentation, each with varying degrees of (financial) cost and technical complexity [155]. The latter alludes to the ease with which arising gait outcomes can be attained by those with a e.g., non-computing or engineering background. Typically, higher cost devices may provide greater ease to attain many gait outcomes. Conversely, lower cost devices may provide barriers to more regular adoption, as they can be less well complemented with proprietary software, requiring bespoke tools created by engineers or computer scientists. However, the financial implications may ultimately help turn the tide, especially with a greater trend towards open software tools for a non-computing audience.

The AX3 has been of particular interest for use in affordable healthcare as it is developed under Open Movement (OM, <https://opendatahandbook.org/glossary/en/terms/open-movement>), which is of growing interest as clarification and transparency on how wearables are created for generating digital biomarkers like gait outcomes are of increased importance [56,57,156]. OM fosters open-source code for firmware and software made available under a BSD 2-clause license (<https://opensource.org/licenses/BSD-2-Clause>), while the hardware (e.g., PCB designs), enclosure designs and documentation are made available under a Creative Commons 3.0 BY Attribution License (<https://github.com/digitalinteraction/openmovement>), to reduce costs and overcome black-box development [34]. Investigation of these more transparently developed wearables will be key to see their pragmatic use in mTBI management. Previously, the AX3 has shown promise for use in low-resource settings to yield pragmatic gait data across a holistic battery assessment of motor tasks [4,19–22]

This chapter has two aims. Firstly, this study aims to investigate a new IMU-based wearable developed under OM (AX6) as a pragmatic tool to instrument motor assessment in a low-resource setting. To do so I investigate its robustness to quantify a common gait task in comparison to another OM-based wearable (AX3). The AX3 was chosen as it is (i) validated in a range of motor capability/functioning studies with use of previous algorithms to be implemented here [132,157–159] and (ii) the most suitable comparative reference where instrumented walkways or 3D motion analysis would not be suitable [160]. The second aim is to then explore the AX6's utility to distinguish groups, specifically those with recent SRC history versus those without within the same low-resource setting. I hypothesize that data from the AX6 will provide robust motor assessment outcomes, plausible objective digital gait biomarkers that may be useful to aid SRC management.

4.3 Methods

4.3.1 Participant recruitment

University students were invited to take part in this study. Inclusion criteria included ≥ 18 years, English as a first language and with no impairment which would prohibit them from safely performing functional tasks. Those interested were then given a participant information sheet which detailed the study. Ethical consent for the project was granted by the Northumbria University ethical committee

(Reference: 3672). Shown in Appendix 2, all participants gave informed written consent prior to testing, which took place at Northumbria University Sport Central, Newcastle-upon-Tyne.

4.3.2 *Equipment*

Supervised assessment was conducted using the low-cost/accessible AX6 (Axivity. 2.3×3.3×0.8 cm, 11g: <https://axivity.com>). The AX6 has configurable tri-axial accelerometer (± 2 -16g) sensor (Bosch, BMI160) with variable sampling capabilities (e.g., 50 or 100Hz), set via proprietary software (OmGUI¹). Here, the AX6 was programmed to ± 8 g, 250°/s and 100Hz. The AX6 and reference device were placed as close as possible to the 5th lumbar vertebrae (L5) with double sided tape (Hypafix) to quantify all tasks.

The AX6 was placed to the right of L5, while the reference was placed to the left, Fig. 1. L5 was chosen based on algorithms used (section 1.3.5). Participants wore the AX6 and reference continuously. Manual timed recordings were taken for completeness as this method is often used in low-resource settings to establish validity. Here, we also use manual recordings to provide insight to those investigating wearables for functional testing, highlighting where discrepancies may arise between methods. Upon completion of recording, participants were verbally asked if they found the devices comfortable to wear during all assessments. The AX6 and AX3 were time synchronized from the same research computer.

4.3.3 *Reference standards*

The previously validated accelerometer only sensor based (ADXL345, Analog Devices) AX3 (2.3×3.3×0.8 cm, 11g) wearable was used (located beside the AX6 on L5, Fig. 9). The AX3 was programmed similar to the AX6 (± 8 g, 100Hz) via proprietary software. The AX3 was previously investigated and validated for use during physical functional assessment in laboratory and low-resource settings [70,159]. In brief, the referenced studies studied the AX3 in comparison to video, instrumented walkway and direct observation to assess its suitability for physical functioning assessment. For example, the laboratory study used video data to segment periods of walking to compare young adult (28.6years) AX3 derived gait characteristics to a GaitRite system with results showing good to excellent agreement between both.

Observational pen-and-paper timings with a stopwatch were taken by me during all testing. Manual timings were taken for completeness as this method is often used in low-resource settings to establish validity. Upon completion of recording, participants were verbally asked if they found the devices comfortable to wear during all tasks. The AX6 and AX3 were time synchronized from the same computer. After testing participants were asked about wearing wearables and the general level of comfort.

¹ <https://github.com/digitalinteraction/openmovement/wiki/AX3-GUI>

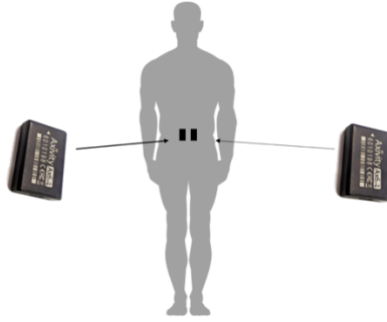


Figure 9: Attachment of the AX6 (left) and reference device (AX3, right) on the 5th lumbar vertebrae (L5).

4.3.4 *Experimental protocol*

Here, I adopted a similar protocol as previously presented [70]. (Please note that the published online version of this study [161] details a greater number of motor tasks and associated algorithms, but gait is presented for the purposes of this thesis only).

Here, the typical outcome of interest is the total distance walked in 2mins which is a widely implemented and useful methodology within motor assessment and the recommended amount of time to capture gait [162]. The task consists of participants walking continuously and as fast as they can but without running. The route consisted of walking back and forth around cones (10m apart). Wearable-based total distance walked was calculated by summing total step length i.e., Algorithm A and C, Table 3. For observational/manual records, the number of laps were counted, and the remaining portion of a lap measured.

4.3.5 *Previous SRC history*

All participants' SRC history was self-reported by the individual and with consent of participants verified against university medical records to ensure accuracy. Groups consisted of those with a previous SRC (pSRC) and no previous SRC (npSRC).

4.3.6 *Algorithms*

Raw IMU data were manually segmented via MATLAB[®] (R2020a, MathWorks Inc., Massachusetts, USA) *ginput* function, made readily possible by the identification of hop/jump data peaks examined from visual observations. Asking participants to hop/jump before each task generated acceleration peaks, not representative of data acquired during tasks.

Data were analyzed with previously validated instrumented motor assessment algorithms [159], Table 3. For example, raw vertical acceleration was filtered by integrating and then differentiating using a Gaussian continuous wavelet transform (CWT) to examine signal local minima, which corresponded to initial contact (IC) times during gait. Subsequently, final contact (FC) events were identified as the signal maxima obtained from a further CWT [145]. Additional IC and FC details can be found elsewhere [132]. (Table 3) was used to deriving temporal gait outcomes.

Once IC and FC were correctly estimated, the inverted pendulum model was used to calculate step length and therefore total distance covered [138,140]. In brief, use of the same inertial data located on L5 can track the center of mass (COM) trajectory during walking to predict amplitude and timing of pelvic displacement (Algorithm D, Table 3). Full details of algorithms and processes are detailed elsewhere [2].

4.3.7 Statistical analysis

Data were tested for normality and linearity of distributions by plotting and inspecting histograms and Quintile-Quintile (Q-Q) plots, respectively. Differences between pairs were found to be normally distributed and so Pearson’s correlation was used to assess linear correlations. Paired sample t-tests are commonly used to test differences between means and whether two samples are different from each other and used here to test for differences between AX6 and references (AX3 and manual). Bland-Altman plots help compare agreement (mean differences) between e.g., technologies ([163] and were used to investigate device limits of agreement (LoA) between the AX3 to AX6. For all analysis, statistical significance was set at $p < 0.05$.

4.4 Results

Twelve participants were recruited (12 male, 20 years \pm 0.82, 181.69 cm \pm 6.84, 91.01 kg \pm 10.59). All participants reported no issues/problems with any wearable, stating they were comfortable to wear during the gait task. During testing, participants wore their usual footwear/shoes.

Table 3. Algorithms and features for gait assessment

Algorithm	Description, used in gait tasks #1 and #2	Representation
A	Detecting initial contact (IC) and final contact (FC) times from gait cycle	$W(a, b) = \frac{1}{\sqrt{ a }} \int_{-\infty}^{\infty} x(t)\psi * \left(\frac{t-b}{a}\right) dt$ <p>The transformed signal is a function of two variables b and a, which are the translation and scale parameters, respectively. The transforming (wavelet) function ($\psi(t)$) is defined as the ‘mother wavelet’</p>
B	Step length (using IC/FC detection)	$\text{Step length} = 2\sqrt{2lh - h^2}$ <p>Changes in height (h) can be calculated (double integration of av) in which l refers to the pendulum length (i.e. height of the inertial wearable from the ground to place of attachment)</p>
C	From estimated IC/FC data, where i denotes an incremental value within the array	<p>Step time (i) = IC (i + 1) – IC (i); Stance time (i) = FC (i + 1) – IC (i); Stride time (i) = IC (i + 2) – IC (i); Swing time = Stride time – Stance time.</p>
D	Estimating pelvic displacement (h) derives step length and consequently step velocity	<p>Step length = $2(\text{sqrt}(2*(\text{Wearable Height}) * h - h^2))$; Step velocity = Step length / Step time;</p>

Table 4. Demographics of those with no SRC history and those with a SRC history

Characteristic	npSRC (n= 9)	pSRC history (n=3)	Independent samples t test p
Age (years)	20.5 (0.87)	21 (0)	0.43
Height (cm)	181.8 (7.9)	186.5 (8.4)	0.23
Mass (kg)	92.12 (4.36)	93.9 (4.36)	0.78
Number of previous concussions	-	2.3 (1.9)	-
Days Since last Injury ^a (n)	-	180 (431)	-
Return to Play from last injury (days)	-	18 (2.9)	-
Position: Back (Bk), Forward (F)	Bk (5) F (4)	Bk (1) F (2)	-

4.4.1 Total distance

There was a significant ($p < 0.01$) positive correlation ($r = 0.95$) between AX6 and AX3 reference for total distance walked but total distances were significantly different ($p < 0.01$), Table 5. Bland-Altman (Fig. 2iv) shows moderate agreement with no outliers outside the upper or lower LoA. Significant differences were also found between AX6 and manual estimations ($p < 0.01$).

4.4.2 Spatial and temporal gait

There were strong correlations between devices for all spatial and temporal characteristics ($r > 0.72$). No significant differences were found in step time ($p = 0.60$), stride time ($p = 0.60$), swing time ($p = 0.78$), stance time ($p = 0.52$) or step velocity ($p = 0.38$), Table 5. However, step length showed a significant difference ($p < 0.01$). Bland-Altman analysis was conducted for each outcome, Fig. 10. For example, stride time (Fig. 10-ii), showed good to excellent agreement with very narrow bias in mean difference and no outliers.

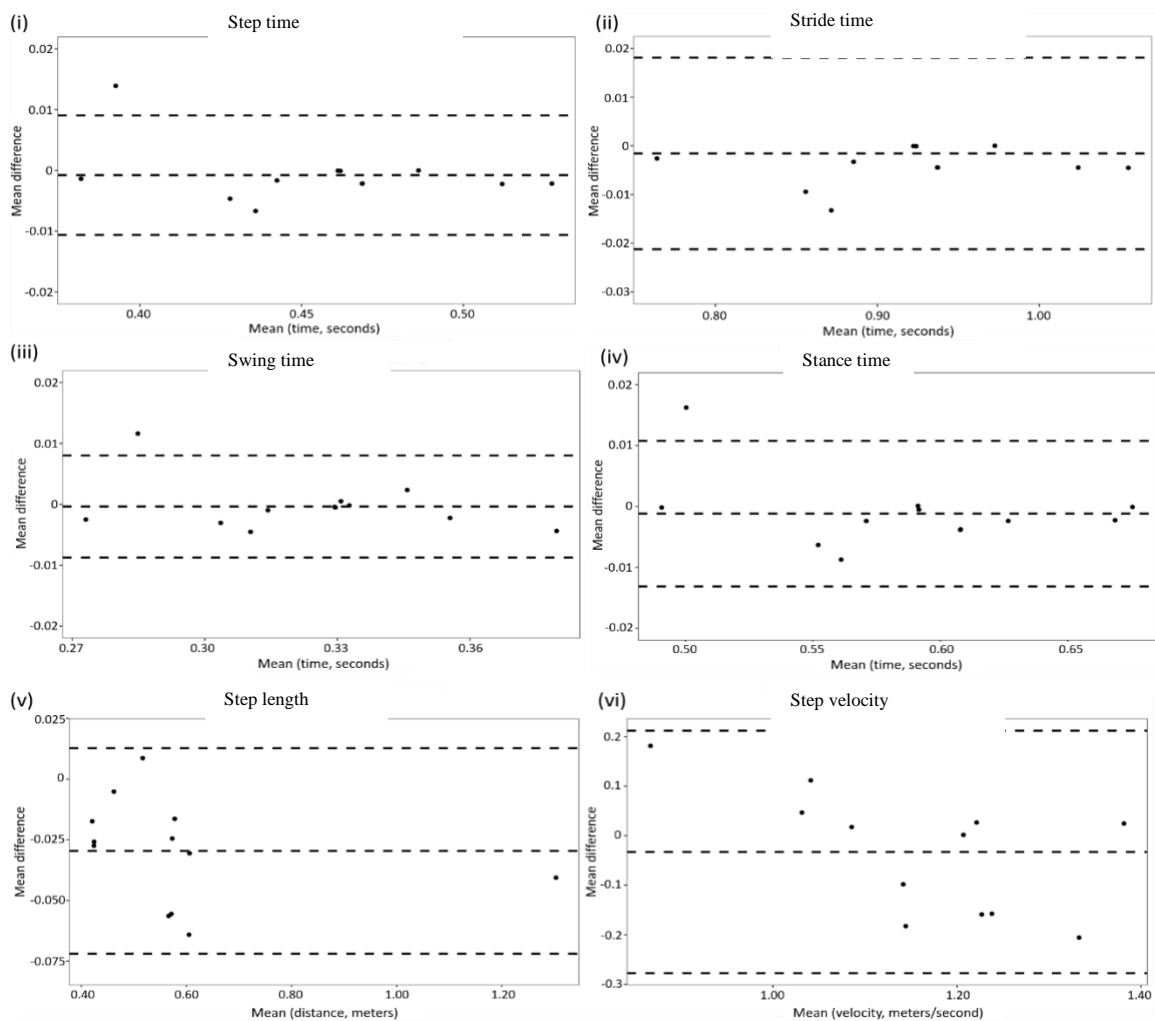


Figure 10: Bland-Altman plots showing agreement between AX6 and reference device for spatial and temporal gait characteristics/biomarker during the 2-minute walking task (i) step time (s), (ii) stride time (s), (iii) swing time (s), (iv) stance time (s), (v) step length (m) and (vi) step velocity (m/s)

Table 5. Temporal and spatial gait characteristic estimations from AX6 compared to references

Characteristics	AX6	Reference (AX3)	Pearsons correlation		Paired sample t.test
	Mean \pm SD	Mean \pm SD	<i>r</i>	<i>p</i>	<i>p</i>
Total distance (m)	140.57 \pm 16.01	133.85 \pm 15.42	0.95	0.00*	0.00*
2min walk (Single task)	Step time (s)	0.46 \pm 0.04	0.99	0.00*	0.60
	Stride time (s)	0.91 \pm 0.08	0.99	0.00*	0.60
	Swing time (s)	0.32 \pm 0.03	0.99	0.00*	0.78
	Stance time (s)	0.59 \pm 0.06	1.00	0.00*	0.52
	Step length (m)	0.55 \pm 0.08	0.72	0.01*	0.00*
	Step velocity (ms ⁻¹)	1.18 \pm 0.18	1.14 \pm 0.11	0.76	0.00*

4.4.3 Distinguishing groups

No significant differences were found in step time ($p=0.1$), stride time ($p=0.1$), swing time ($p=0.06$), stance time ($p=0.14$) or step velocity ($p=0.42$). However, step length showed a significant difference ($p<0.05$) potentially indicating its usefulness in differentiating those with SRC history and those without, this is supported by large effect sizes of (1.8) across the remaining variables.

Table 6: Temporal and spatial gait characteristic, SRC history and no history 2-minute walk

Characteristics	npSRC (n=9)	pSRC (n=3)	Independent sample t test	
	Mean \pm SD	Mean \pm SD	<i>d</i>	<i>p</i>
Total distance (m)	134.9 \pm 12.89	157.31 \pm 12.37	1.6	0.04*
2min walk (Single task)	Step time (s)	0.44 \pm 0.04	1.2	0.1
	Stride time (s)	0.89 \pm 0.08	1.2	0.1
	Swing time (s)	0.31 \pm 0.03	1.3	0.06
	Stance time (s)	0.57 \pm 0.06	1.1	0.14
	Step length (m)	0.52 \pm 0.08	1.8	0.02*
	Step velocity (ms ⁻¹)	1.15 \pm 0.21	0.5	0.42

4.5 Discussion

This study investigated a new OM inertial-based wearable (AX6) as a suitable tool within instrumented motor assessment in a low-resource setting. Outcomes from the AX6 were compared to those from previously validated reference (AX3) and manual recordings. Findings suggest that the AX6 may be a suitable digital tool for use in low-resource settings to quantify gait. The AX6 can capture robust raw data transparently, an emerging research priority [57,164]. Additional analysis comparing those with recent SRC history and those without suggest, that gait may be a useful method for distinguishing those cohorts. This suggests the technologies usefulness to meet current challenges in low-resource, community settings for personalised mTBI management (PoI 1 to 3).

4.5.1 Validation

There were no significant differences between the AX6 and reference device for temporal gait outcomes or velocity derived. Although the spatial outcome (step length) was significantly correlated, there was a significant difference between mean values. Again, this can be attributed to the reasons highlighted in section 4.1 i.e., inverted pendulum model and protocol used.

Compared to manual recordings, both wearables underestimated total distance. There are some key issues pertaining to the difference of total distance walked during this test. The inverted pendulum model is optimized for straight line linear walks only [138,140]. Authors of the proposed model describe how the center of mass and pelvic displacement approximately correspond to sinusoidal movement patterns. However, the underlying pattern of acceleration during walks in our protocol would not have been linear and so could not be perfectly modelled by a sinusoidal function. That would have been further impacted by the directions given to participants i.e., walking as fast as they could, where walking speeds would have fluctuated during all endurance walks due to e.g., fatigue. Moreover, inconsistent angular changes (left or right turns) during which participants rounded ends of the 10m course would negatively impact functionality of the inverted pendulum model. That is because wearables placed on either side of the vertebrae would experience different biomechanical properties of foot placement of up to many centimeters which would accumulate into many meters over the duration of a 2min walk. Thus, linear acceleration and wearable placement will not have been perfectly described by a sinusoidal function here. When the raw acceleration signals were examined, we observed that not all IC/FC events were suitably identified at the moment of a turn (identified from raw gyroscope data) which negatively impacted the algorithms' ability to correctly estimate steps length compared to straight line walking. This may have been attributed to location around L5 and direction of turning at the end of each walk.

Although the AX6 ($140.57\text{m} \pm 16.01$) compared to wearable reference ($133.85\text{m} \pm 15.42$) showed statistically significant differences ($p < 0.01$), the mean difference was approx. 6.7m with a 95% confidence interval (3.6m to 9.9m). With total walking distances ranging from 115m to 170m, this degree of accuracy may be deemed suitable, especially as the protocol involved walking back and forth. However, such accuracies should be investigated as to their suitability in examining individual performance variation/change due to e.g., mTBI in a sporting context. Significant differences between AX6 and manual recordings ($196.67\text{m} \pm 19.72$) can also be attributed to the protocol adopted here. The AX6 sensor being sensitive to linear deviations of gait (rounding/turning past the cones) and wide movement path around cones, which may negatively impact on peak detection accuracy and subsequent IC/FC estimations. Clearly asking participants to complete the task in a linear fashion with 180-degree may help to overcome these overestimations, but this would limit the clinical relevance and ecological validity as humans naturally complete lots of turns or rarely walk in a straight line [86]. Nevertheless, current use of existing wearable algorithms to quantify step length with any walking protocol would suggest useful proxy values as outcomes to gauge total distance walked.

On average, the AX6 ($4.89\text{s} \pm 0.76$) recorded slightly lower times (0.15s) compared to the reference ($5.04\text{s} \pm 0.87$). This is despite both devices utilising the same algorithm to identify IC and FC times to estimate total time. The slight discrepancy may be from wearable placement, both placed laterally near L5. Visual examination showed slight variations in accelerometer signals (raw data). This was perhaps due to the left and right placement along/on the L5 vertebrae. Additionally, the AX6 uses a different inertial sensor (BMI160) compared to the AX3 (ADXL345). Perhaps differences in sensor manufacture contribute to slight signal deviations, impacting end values here as well as in all physical capability tests. Given slight signal discrepancies may arise between sensor signals (BMI160 vs ADXL345), these could be exacerbated by their differing attachment location. Thus, use of different wavelet scale parameters could improve signal to noise ratio without losing resolution enhancement for different sensor types and wear locations, warranting future investigation [165]. Different wavelet approaches have been examined elsewhere. For example, previous work examined a plethora of wavelet approaches

for one aspect of physical functioning (i.e., postural transitions)-noting possible accuracy improvement through careful wavelet type selection-[166]. Here, a CWT with a Gaussian wavelet function was used for the purposes of detecting IC and FC events within the gait cycle. Alternatively, it has been proposed that IC and FC accuracy could be improved by using a bi-orthogonal spine wavelet-[70,159].

Timing differences were $>0.7s$ between the AX6 and manual recordings. Large discrepancies and significant difference is primarily due to the subjective nature of manual assessment and errors within researcher timing on correctly identifying initial as well as final contact to signify the start and end of the trial, respectively.

4.5.2 *Useability*

Participants were able to wear these devices for the duration of the lab visit without complaints or negative effects. However significant set up time was associated with attaching devices to the lower back with Hypafix tape as described in the methods and required assistance of a researcher/physio to re-attach. This may suggest usability for short testing periods such as laboratory assessment, but further research is required if suitable for longer term assessment such as in free-living environments.

4.5.3 *Distinguishing groups*

My preliminary results showed that a 2-minute walk may have mixed utility in differentiating those with mTBI/SRC and those without. As highlighted in the results, there were no significant differences found in step time ($p=0.1$), stride time ($p=0.1$), swing time ($p=0.06$), stance time ($p=0.14$) or step velocity ($p=0.42$). However, total distance walked, and (as would be expected) step length showed a significant difference ($p<0.05$), yet this was also significantly different between devices. This may be due to the approaches used to calculate step length being optimised for lower speed linear walking and subtle deviations or drift when walking or in turns leading to small discrepancies between reference and AX6 devices [167,168]. Similarly, there may be differences in type of walking or pattern e.g., non-uniform walking pattern which may also lead to small discrepancies.

Despite there being no significant differences between groups for almost all variables, the presence of large effect sizes of (1.8) across the majority of variables on a small sample size is of interest. This is important initial signal in the wider context of my thesis and provides an important contribution to PoI 2 about the accuracy or consistency of wearables and warrants further investigation across larger cohorts in later chapters.

4.5.4 *Limitations and future work*

One limitation of this study was the small sample size ($n=12$), which may limit the ability to detect small differences between variables and groups. Future work should include a larger and more substantial sample size to increase variability in participant data. Moreover, this study was conducted on young, fit healthy males only. Similar studies examining use of the AX6 wearable should examine the device between genders to determine the wearables wider suitability/fit-for-purpose. Here, I aimed to assess the usefulness of the AX6 to generate accelerometer-based gait outcomes in young adults in a low-resource setting. Going forward, the AX6 (accelerometer and gyroscope data) should be examined for its suitability to better quantify digital data biomarkers for clinical validity across measures of gait e.g., gait and turning outcomes as well as during free-living. Indeed, use of the gyroscope sensor could help automated segmentation of all tasks.

Although beyond the scope/aims of this study, a future recommendation would be for an analytical validation to be performed via suitable bench testing approaches to thoroughly investigate raw data from both devices. For example, a previous approach compared the acceleration output of an ADXL202 to a potentiometer within a pendulum-based device [169]. The referenced study used a bench top rig (ADXL202 embedded within the center of a pendulum mass and compared output to the rotating shaft of a potentiometer from which the pendulum was suspended) to subject the accelerometer to a known

repeatable, varying acceleration signal similar to that experienced in gait. Such an approach aids verification approaches to device/sensor suitability for movement similar to motor assessment.

4.6 Conclusion

This study investigates the use of a new Open Movement IMU (AX6) for gait assessments in young adults within a low-resource setting. Compared to a well validated reference, good to excellent agreement for gait outcomes were found. Findings suggest the low-cost AX6 is a suitable digital tool to provide accessible and robust raw data to quantify a motor task i.e., gait in a non-bespoke (clinical) setting. In addition, I explored whether gait can it distinguish between groups (recent SRC history and no SRC history), finding that step length may be useful in differentiating groups. This provides an initial step into investigating and stratifying which tasks may be useful for wider clinical utility.

Although my sample size was small, preliminary results suggest the AX6 may be scalable for data collection on larger studies in community environments. This directly contributes to PoII, whereby affordability of assessment is important within current SRC/mTBI challenges. Current reliance on traditional assessment may be limiting opportunity to understand patterns and the nature of motor impairments in mTBI. Using objective inertial wearable data may also help mitigate the error introduced in subjective assessment by an observer.

4.6.1 *Passive monitoring tools: Next steps*

In chapters 1 and 2 the suggestion of altered behaviour when under direct observation of a clinician was introduced. It is widely known that assessment under observation can induce the *white coat syndrome*, also known as the Hawthorne effect [170]. This is something alluded to by Will Hooley (Chapter 1) and often witnessed by myself during my physiotherapy work with rugby teams. Specifically, Will Hooley described how:

"...players push themselves too hard and lie about their symptoms to enable them to RTP"

Additionally, he (Mr. Hooley) progressed to describe how:

"...players can also overthink how they are feeling, making them feel worse than they are. Naturally, players want to continue playing/training and so medics must see through these"

To overcome, my research will be informed by other areas of inertial wearable research where there is a trend to move gait assessment beyond the well-controlled environment of a supervised setting to overcome strategies to improve their performance or compensate [160,171]. The move to free-living, *habitual* assessment/monitoring was proposed in Chapter 2 and will be a notable contribution from Chapter 5.

The use of inertial-based wearables to instrument motor tasks (like gait) can be useful to provide objective data continuously in habitual environments. Here, I suggest that may help overcome player strategies during supervised and contrived snap-shot assessment [172]. Accordingly, the next chapter explores the novelty of using the same wearable investigated here for remote motor/gait assessment i.e., in habitual free-living environments.

Chapter 5: Habitual motor assessment: A single-subject investigation

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The journal article “*Exploring Inertial-Based Wearable Technologies for Objective Monitoring in Sports-Related Concussion: A Single-Participant Report*” was published in **Physical Therapy and Rehabilitation** in 2022 (URL: <https://doi.org/10.1093/ptj/pzac016>)

5.1 Introduction

As detailed in chapter 2, digital technologies are suggested as viable contemporary means to continuously and objectively measure outcomes which could augment traditional snapshot mTBI assessments [34,173]. Chapters 3 and 4 focused and showcased the use of inertial technology approaches to quantify gait which may have novel utility and value in mTBI. Additionally, chapter 4 evidenced that use of financially attainable and accessible wearables to produce objective gait outcomes via the OM initiative, which could be a valid and viable pragmatic option. In chapter 4, I suggest that the same wearable technology could be used to see through any potential strategies by players to improve/alter motor/gait outcomes during supervised assessment. That suggestion is motivated by other fields of inertial gait research describe a desire to move away from contrived supervised assessments, going beyond the lab for a remote monitoring approach. That would help to overcome snap-shot assessments as also highlighted in chapter 2.

Going beyond supervised assessment and into the home to gather habitual data is now a tangible research methodology. That is due to the widespread availability of wearables and other associated technologies (e.g., smartphone and apps) which could gather (high-resolution) habitual data continuously for many days [35]. The SCAT5 is a snap-shot assessment tool, confounded by subjective approaches of manual rating and self-reporting during each subcomponent/test [174–176]. Thus, making it extremely challenging to accurately/objectively and transparently monitor and assess SRC impairments. This justifies demand for new objective methods to better track SRC recovery and better inform RTP.

To my current knowledge, no study has examined the use of inertial-based wearable for (holistic) SRC assessment under habitual conditions. Using these disruptive digital technologies would enable high resolution data capture to augment snap-shot assessment as well as remote monitoring to assess habitual SRC impairments over longitudinal periods. In short, utilizing digital approaches to continuously monitor mTBI impairments (e.g., gait) may enhance current methods and deliver more objective and personalised mTBI assessment digital (bio) markers.

The purpose of this single-participant report/study was to explore the feasibility and potential of a wearable IMU to improve SRC/mTBI assessment in a rugby player. Remote monitoring was conducted to investigate how arising data could augment traditional approaches. The study participant completed traditional supervised/reference testing (SCAT5) yielding primary outcomes. Then, the participant undertook supervised instrumented and remote assessment yielding secondary (digital) outcomes pre and post SRC. I suggest that using supervised and remote (free-living) assessment with a wearable IMU will yield more insights compared to traditional SRC assessment alone. (Please note the online published version of this study goes beyond gait to showcase a wider array of possible data to the research audience. Some of those data are presented in Appendix 4)

5.2 Methods

5.2.1 Participant recruitment

Inclusion criteria consisted of: ≥ 18 years of age, English as a first language and with no impairment which would prohibit them from safely performing the supervised task or remote assessment. Ethical consent for the project was granted by the Northumbria University ethical committee (Reference: 3672). The participant was given an information sheet which detailed the study, and the subject gave informed written consent prior to testing. All supervised testing took place in a generic room at Northumbria University Sport Central, Newcastle-upon-Tyne during the 2019 and 2020 season.

A player who sustained a SRC was chosen at random from the larger pool of male university rugby union players. A male participant was selected (20 years, 175cm, 77kg) for assessment. This player had been followed up after sustaining a SRC/mTBI within 24 hours. At the time of testing, he had completed 16 years of full-time education and self-reported a total of five SRC with his most recent prior to testing

occurring in Spring 2019. University medical records detailed that his recovery time from previous SRC was 19 days.

5.2.2 Technology

The IMU-based wearable assessment was conducted using the low-cost AX6 (Chapter 4). The AX6 was placed as close as possible to the 5th lumbar vertebrae (L5) with double sided tape as described in Chapter 4. The subject wore the AX6 continuously for the duration of supervised (30 minutes) and remote assessments (the latter comprising 24 hours at each timepoint).

5.2.3 Design phases: Experimental protocol

The participant was assessed at pre-SRC, post-SRC and once RTP using both traditional (SCAT5) and wearable assessment as described below.

5.2.4 Primary outcome(s) – SCAT5

The SCAT5 was completed by a physiotherapist (me) at (i) baseline (conducted in 2018) as well as, (ii) 1-hour, (iii) 2 days, (iv) 5 days, (v) 12 days and (vi) approx. 2.5 months post mTBI/SRC (Table 1).

5.2.5 Secondary outcomes – Wearable IMU

Data were processed using custom-made and validated MATLAB[®] (MathWorks Inc, Massachusetts, USA) algorithms to estimate supervised and remote gait characteristics [132,153]. Raw IMU data were examined pre-SRC, post-SRC (1 day) and once RTP (28 days post-SRC) as follows:

1. Supervised (laboratory) gait assessment:

The participant walked continuously and as fast as he could (without running) back and forth around cones (10m apart) as part of the two-minute walk test [177,178]. Wearable timing began upon the first step. Recording ended after the subject completed the walk (manual, by stopwatch) or last purposeful footfall (as detected by wearable). The latter was determined from the vertical acceleration (a_v) exceeding a predetermined threshold [86].

2. Gait characteristics:

Raw IMU accelerometer data were used to identify the initial contact (IC) and final contact (FC) times within the gait cycle [145]. IC and FC estimation facilitated quantification of step time (seconds, s) where a walking bout has been previously defined as and ≥ 3 steps with consecutive steps within a 0.25 to 2.25s window [118]. Subsequently, variability and asymmetry gait characteristics were quantified from alternate values within an array of step times. Here, we examined all gait data (from gait initiation to termination) in bouts/periods of gait that were approx. 2mins to be comparable with lab-based gait. As described the total distance walked in 2mins is a widely implemented and useful methodology within a motor assessment and provides the optimal gait capture gait protocol [162]. For exploratory purposes we quantified two variations of gait variability which are common in the literature, as follows:

- i. Variability (Var): The combined standard deviation of left and right steps was calculated by taking the square root of the mean variance of the left and right steps. This method avoids confounding step-to-step variability with variation originating from asymmetry between left and right steps [179]. Here, true left and right footsteps were not explicitly identified, and so alternate values were chosen.
- ii. Standard deviation (SD): The SD of all steps were calculated for left and right i.e., left and right were not separated out as alternating values.

Asymmetry was calculated as the absolute difference between left and right steps. Again, true left and right footsteps were not explicitly identified, and so alternate values were chosen.

3. Remote gait assessment (post-SRC and 1-month post-SRC once RTP)

The wearable IMU was worn continuously for 24-hours, with the participant asked to perform their normal/habitual routine. A validated algorithm [153] quantified gait/walking bouts where for the purposes of this study, gait bouts ≥ 120 s/2-min were examined only. Once possible gait bouts were detected, the same gait characteristics were calculated as during supervised assessment (above).

5.3 Results

5.3.1 Primary outcomes

Post-SRC symptom severity data shows a sharp increase in symptom score 1-hour post injury (87) peaking at day 2 post injury (106) before decreasing and returning to normal at day 12 (0). Balance errors also peaked (11) shortly after injury before gradually decreasing 12 days post injury. Similarly, immediate memory returned to normal function, 5 days post injury. The subject was cleared to RTP and contact sport by an independent general practitioner after 20 days. At re-assessment (2.5 months after injury) there was a decline in some SCAT5 outcomes (decreased well-being and increased balance errors).

Table 7. SCAT5 Pre-SRC, Immediately Post-SRC and 2-months later

Measure	Pre-SRC	Post-SRC					RTP
	Baseline	1-hour	1-day	2-days	5-days	12-days	2.5 months
Symptom number (out of 22)*	0	20	18	22	7	0	0
Symptom severity score (out of 132)*	0	87	63	106	21	0	0
Percent wellbeing (out of 100%)**	100	50	0	70	75	100	80
Orientation (out of 5)**	5	4	0	5	5	5	5
Immediate memory (out of 15 or 30)**	19/30	4/15	0/15	14/15	15/15	15/15	15/15
Concentration (out of 5)**	0	1	0	3	3	2	3
Neuro Exam (abnormal or normal)	normal	<i>abnormal</i>	<i>abnormal</i>	normal	normal	normal	normal
Balance errors (out of 30)*	12	16	30	11	4	1	8
Delayed Recall Out of 5 or 10)**	4/10	0/5	0/5	2/5	2/5	3/5	5/5

* A lower score is better (more normal)

** A higher score is better (more normal)

Green/bold data - the player returned to baseline levels

Red/*italic* data – the player scoring worse than baseline

5.3.2 Secondary outcomes

5.3.2.1 Supervised gait (2-minute walk)

Wearable IMU assessment was well tolerated by the participant and no concerns of discomfort were raised. There were differences for gait pre-SRC, immediately post-SRC and 2.5-months follow up, respectively. Results show increases in step time (0.461s, 0.491s, 0.529s), step time variability (0.018, 0.151s, 0.255s) and step asymmetry (0.012s, 0.003, 0.036s) for baseline, post-concussion and 2-months follow up, respectively (Table 7).

Table 8. Gait characteristics from supervised 2-min walk (initiation to termination)

	Characteristic	Pre-SRC	Post-SRC (1-day)	2.5-month post SRC
All gait data (entire 2min walk)	Step time (s)	0.461	0.491	0.529
	Step time variability (Var, s)	0.018	0.151	0.255
	Step time variability (SD, s)	0.019	0.057	0.171
	Step time asymmetry (s)	0.012	0.003	0.036

5.3.2.2 Remote gait

Remote wearable IMU gait assessment showed 4-bouts of (sustained) walking for ≥ 2 mins immediately post-SRC compared to 6-bouts 1-month post-SRC, Table 9. Mean step times were shorter immediately post-SRC compared to 1-month later. There were no clearly observable trends for step time variability between different timepoints but what was observed during gait assessment 1-month post SRC is the difference in variability outcomes for contrasting calculation methods. Asymmetry was notably higher 1-month post SRC, which may have been influenced by some abnormal outliers. Additional data are presented in appendix 4 for further gait characteristic exploration.

Table 9. Remote gait from bouts of walking ≥ 120 s/2-mins (initiation to termination)

		Post-SRC (1-day)					
		Bout 1	Bout 2	Bout 3	Bout 4	Bout 5	Bout 6
		2:43pm	2:51pm	4:33pm	4:36pm		
All gait data	Step time (s)	0.464	0.458	0.462	0.440	--	--
	Step time variability (Var, s)	0.016	0.013	0.041	0.043	--	--
	Step time variability (SD, s)	0.016	0.013	0.041	0.043	--	--
	Step time asymmetry (s)	0.005	0.001	0.004	0.004	--	--
		Post -SRC (1month)					
		Bout 1	Bout 2	Bout 3	Bout 4	Bout 5	Bout 6
		11:47am	11:50am	12:38pm	12:42pm	12:54pm	1:01pm
All gait data	Step time (s)	0.508	0.504	0.486	0.490	0.491	0.489
	Step time variability (Var, s)	0.028	0.025	0.017	0.021	0.016	0.057
	Step time variability (SD, s)	0.033	0.031	0.020	0.024	0.022	0.058
	Step time asymmetry (s)	0.034	0.036	0.022	0.024	0.031	0.008

Var = Variability. SD = Standard deviation

5.4 Discussion

The purpose of this single subject report/study was to examine feasibility and potential of supervised and remote assessment with a wearable IMU to augment traditional SRC assessment. To my knowledge, this is the first study to deploy an IMU-based wearable for mTBI/SRC monitoring during a RTP protocol. Use of IMU-based wearables can yield many objective gait outcomes e.g., step time compared to traditional observational assessment. Free-living/remote assessment with an IMU for gait was well tolerated and may be particularly useful when examining individuals with complex medical and frequent SRC history. Continuous monitoring with wearables over long periods may be required to detect sensitive or subtle deficits that become more evident during habitual behaviours which persist after RTP.

5.4.1 *Enhancing assessment*

My results reinforce the challenges of traditional approaches with the SCAT5 which may not be sensitive i.e., significant ceiling effects (i) to the varied recovery participants experience post-SRC or (ii) useful in dealing with complex recovery trends. Indeed, it is often the case a different clinician administering/recording the SCAT5 at each time point contributing to variation (PoI2). For example, the choice of what cognitive test difficulty (5- or 10-word list), can impact the reliability or consistency in testing, meaning some players being tested on different difficulty ratings/scoring. This is shown in Table 1 whereby the participant was scored initially on the 10-word list at baseline; however, post injury was scored on 5-word lists, making comparison between scores more challenging. As shown in Table 1, SCAT5 outcomes quickly trended to baseline after 12 days. Specifically, there was full symptom resolution and improvement in both cognitive and balance scores (Table 1) indicating progress in recovery. A general practitioner approved RTP (full contact rugby) by day 20 based on those SCAT5 outcomes and (subjective) clinical judgement. The decline in some SCAT5 outcomes (decreased wellbeing and increased balance errors) 2.5 months after injury is difficult to attribute to a specific injury or timepoint. However, it is reasonable to speculate incomplete recovery from initial injury and/or playing through a new/distracting injury to contribute to the decline in outcomes. This highlights how challenging it can be for clinicians to rely on subjective outcomes to assess or judge a player's injury/recovery status.

Addition of a wearable IMU facilitated instrumented assessment was an efficient method to gain a more objective impression of SRC impact and recovery, albeit on motor assessment alone. Data from the wearable allowed investigation into more detailed trends for gait outcomes longitudinally (during recovery and 1-month post-SRC). Specifically, within supervised wearable gait assessment, there were differences for step time immediately post-SRC, consistent with impaired motor control [40]. Unsupervised/remote wearable gait assessment suggested impairments even upon RTP, which could further support an incomplete/full recovery [180].

Wearable IMU assessment afforded the opportunity to yield high-resolution clinical-based gait outcomes such as mean step time and variations (variability and asymmetry) which is not possible with traditional approaches (SCAT5). My exploratory analysis suggests those data may be clinically useful but that it is also important to consider how those outcomes are calculated and presented. Here, I explored two common methods to estimate step time variability which resulted in differences in outcomes even during the same walking bouts, supervised or remote assessment, Tables 2 and 3. The quantification of step time is calculated as the difference between the estimations of initial and final contact within the gait cycle as previously described in chapter 3 and elsewhere [132,140,145]. Step time variability (standard deviation of left and right steps) is estimated via the square root of the mean variance of the left and right steps, and step time asymmetry is calculated from the difference between right and left steps (mean values) [132]. Increased step time variability and asymmetry have been closely linked with impaired or dysfunctional motor control and deficits in similar groups such as mTBI and TBI [181]. One can observe broad changes and trends in step time in other conditions such as Parkinsons disease and chronic mTBI [81,90,182]. However, at present there is a lack of consensus on

exactly what constitutes normal or impaired gait, particularly in SRC/mTBI [183]. Therefore, I am unable to give exact values or be precise about an agreed meaningful clinical change here but will be explored further in later chapters.

This case study also can't be directly compared to studies examining larger cohorts of TBI participants, which observed differences for step time variability pre-SRC and post-SRC. My results also found large step asymmetry 1-month post-SRC, which may be explained by outliers at that timepoint. However, recent research [184] suggests step time asymmetry could also be linked to energy demand and compensatory behaviours due to energy cost of impaired gait [184,185]. My results would align with that research, as step time asymmetry decreased immediately post-SRC, then increased 1-month post-SRC once the participant had RTP.

Overall, the addition of a wearable IMU facilitated instrumented assessment was an efficient method to gain a more representative and insightful exploration of gait trends and recovery. Accordingly, the digital approach helps support PoI3, achieving personalised approach for mTBI management. However, collecting data on more participants is required for a thorough/robust investigation and interpretation of gait (and other physiological outcomes that can be captured with an IMU) during SRC recovery.

5.4.2 *Enhancing RTP decisions*

Traditionally RTP clearance and readiness to RTP is within the realm of a general practitioner or medical professional who uses clinical judgement to form the basis of their opinion. They may use tools such as the SCAT5 to aid in their judgment, but this should not be used in isolation (Chapter 2). Furthermore, symptom resolution is the main driver in RTP [11], with full resolution and the successful navigation of the graduated RTP a necessary precursor before RTP.

Remote assessment using wearables is a unique example of an objective digital method which has been successfully tested in other neurological conditions e.g., Parkinson's disease [90,186]. Remote assessment affords the opportunity for habitual monitoring of a variety of individualised digital (bio) makers such as gait [56]. Adoption of such technology can improve upon episodic data points (e.g., supervised data collection), enabling a more objective and in-depth SRC/mTBI assessment. Remote gait assessment may be more clinically useful and informative than isolated supervised (snapshot, Figure 3) assessment when comparing post-SRC, recovery and RTP.

Alongside the traditional RTP a general practitioner or other clinician would have additional objective data to aid in RTP decision making. Instead of number of balance errors from the SCAT5, the multi average in e.g., gait variability and asymmetry outcomes could be presented and compared to normative and/or baseline performances. Overall, a wealth of additional outcomes could be given. Here within my results, preliminary gait outcomes (step time) suggest use of wearables to quantify some degree of motor impairment upon RTP, suggesting an incomplete recovery of the subject or displaying compensatory gait behaviours. As this is a case study, strong (clinical) conclusions can't be drawn, but the potential value and benefits of remote gait assessment are highlighted and should be considered and explored further in my thesis. (The wearable also provided insight for other motor assessment such as sleep disturbance but is not for investigation within this thesis – Appendix 5)

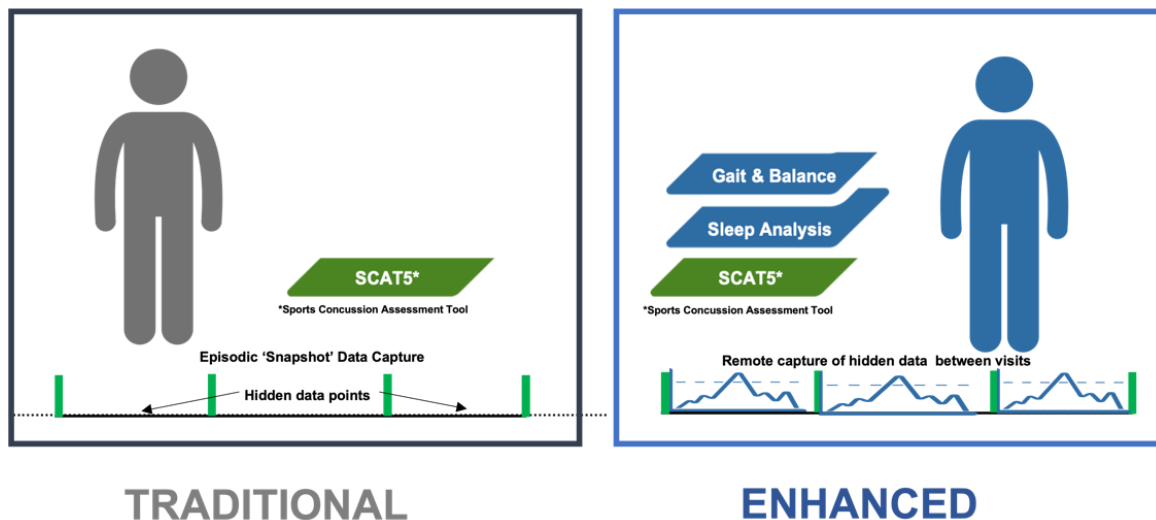


Figure 11: Traditional (SCAT5) versus Enhanced Returned to Play with additional metrics such as gait

5.4.3 Limitations

The limitations of a single subject research include generalizability of study conclusions. There are other extraneous considerations that should be considered. For example, no baseline assessment (e.g., previous injuries) was conducted for wearable assessment, which may impact gait patterns and gait data captured by the wearable. Additionally, this study did not include the use of any self-reported diary relating to physical activity, which has previously been used in free-living activity monitoring to better contextualize (see below) wearable data [187,188] and should be included in future explorations and studies. Furthermore, although the wearable provided rich data, its current form factor has suitability challenges issues for longitudinal use in multiday assessment.

5.4.3.1 Challenge 1: Form factor

As highlighted in Chapter 4, I found the AX6 to be a valid low-cost device suitable for lab-based assessment, however there are substantial challenges pertaining to pragmatics of using the AX6 technology for direct-to-consumer assessment or clinician to consumer assessment. The reasons for this are partly related to form factor, with the AX6 requiring attachment directly to the body via hypafix tape, which may not be applicable or suitable for long periods of assessment. This is particularly challenging for those who live active lifestyles, such as university athletes, and may be participating in a range of different activities e.g., strength training, which would require constant re-attachment with tape or discomfort if worn through these activities. This suggests a device with easier attachment or re-attachment may be more tolerated across larger cohorts of individuals.

5.4.3.2 Challenge 2: OM approach

To process the IMU data requires specialist training and prior experience of IMU data processing [57,156]. Therefore, a current barrier to using IMU data from an OM wearable is the provision of ‘no-code’ software for pragmatic interpretation by clinicians or non-technical skilled researchers [57]. To improve accessibility and transparency of data collection methodologies future research should focus on developing complementary open-source approaches for e.g., gait recognition and spatio-temporal outcomes from all gait bouts, as suggested elsewhere for waist worn sensors [189]. Starting points exist but their approach remains specialised and not configured for everyday use or by those without experience of programming/coding[190,191].

5.5 Conclusion

My results evidence the shortcomings of traditional approaches (i.e., SCAT5) which may not be sensitive e.g., significant ceiling effects (i) to the varied recovery participants experience post-SRC or (ii) useful in dealing with complex recovery trends. This single-subject case study showed wearable assessment can be well tolerated for short periods and yields objective outcomes through remote assessment at different time points, which may have utility in routine and complex mTBI/SRC RTP decisions. Although the wearable (AX6) provided rich data, its current form factor and requirement to be directly attached to the body by e.g., Hypafix tape, may not be applicable for longitudinal use in multiday assessment. Regardless, precise mTBI/SRC motor-based impairments could and should be measured with (inertial) wearables but need refining across more individuals.

Chapter 6: Lessons learned

6.1 Introduction

The purpose of this chapter is to determine how the PoI's (Chapter 1) have been addressed from preliminary investigations (Chapters 2 to 5). Here I outline the lessons learned as part of my research so far in this thesis and introduce the next stage of my research to provide a unique contribution to knowledge while examining my thesis statement / research hypothesis.

6.2 Lessons learned and the next stages of the thesis

There have been some important and practical findings gathered to this point to inform mTBI management. In chapter 1 a rapid landscape analysis via a semi-structured interview approach was taken to understand the current unmet needs arising from contrasting perspectives, challenges in the context of rugby union on the pitch and from the sideline across the professional to amateur spectrum. Three PoI's emerged as important levers/mechanism for change, namely;

- PoI1: finance and resources,
- PoI2: access, scalability and consistency (inc. accuracy, subjectivity vs. objectivity)
- PoI3: personalised assessment and increased patient/player involvement

Those PoI's led me to hypothesise that digital technologies may enable affordable (PoI1) mTBI management while ensuring continuity (PoI2) and offering more objective personalised assessment to support traditional approaches (PoI3).

6.2.1 Addressing PoI1, PoI2 and PoI3

Chapter 2 provided a critical analysis of the literature into the traditional and more contemporary methods relating to mTBI/SRC. Focus was on assessment techniques to better understand the current state of the art, with a goal to harmonise key work to shed light on research gaps relating to mTBI management. Affordable (low-cost) digital technologies were identified in inertial wearables and the opportunity for (i) gait as a useful assessment tool and (ii) a need for multimodal assessment. Accordingly, chapter 3 provided a thorough investigation and understanding of inertial/IMU through a scoping review to inform key technical details for use by me later in the thesis. Chapter 4 helps to address *PoI1* and *PoI2*, use of an affordable wearable in a low-resource environment to be a valid and pragmatic tool to inform mTBI motor-based (gait) assessment with promise to distinguish those with a recent mTBI/SRC. Chapter 5 deployed the same affordable wearable but beyond a supervised setting, into remote/habitual mTBI assessment as part of a single subject report. That chapter showed evidence of how habitual gait data could be captured, overcoming player/patient strategies to “cheat” symptoms (i.e., more traditional mTBI/SRC checklists) and providing personalised monitoring (*PoI3*). Although the affordable wearable was useful/acceptable for short assessments (Chapter 4), it was deemed not currently fit-for-purpose during longitudinal deployment (Chapter 5).

6.2.1.1 Move towards user friendly technology

Significant pragmatic and computational challenges were found when using the AX6 inertial wearable, namely the form factor and mode of attachment with e.g., Hypafix tape. I believe that approach would restrict successful long-term deployment/remote assessment due to lack of adherence by study volunteers. Accordingly, I therefore sought an analogous device which would have the same underlying (electronic) hardware but offer an alternative, more user-friendly attachment method.

The MoveMonitor (McRoberts, Netherlands⁴¹; 106.6×58×11.5mm, 55g) was sourced and will be used for the remainder of this thesis, unless otherwise stated. It comprises an equivalent inertial technical specification (accelerometer and gyroscope with comparable range and sampling frequency

capabilities compared to the AX6). Importantly the MoveMonitor is also worn on L5 but offers an easy-to-use belt attachment (elastic belt with clip) [192,193] and has been used extensively for motor assessment while being considered a valid technology for use in controlled/lab/clinic and free-living environments. Critically, recent findings from the EU Mobilise-D study [3–7] have reported that gait algorithms used in this thesis to be device agnostic, meaning they can be used interchangeably with validity on different inertial technologies.

At the time of receiving quotes and purchasing the technologies (2019/2020), the AX6 was considered affordable (approx. £150) while MoveMonitor was deemed less affordable, primarily due to the proprietary software that needs to accompany the physical wearable for programming, data download and storage (approx. £260 + £340 = £500). Though price differences have since fluctuated for both technologies, the fundamental principle presented in this thesis remains that affordable inertial wearables exist and (as presented elsewhere) algorithms can be used interchangeably. However, opportunities do exist, and they will be presented in Chapter 11.

6.2.2 *A contemporary approach*

Pervasive mTBI/SRC assessment techniques such as the SCAT5, collect self-reported/subjective measures are restricted to highly controlled supervised environments such as physiotherapy clinics or health centers. Although useful data are collected, these assessments are unable to capture habitual behaviors/trends and therefore omit a wealth of data which could be captured by non-obtrusive digital approaches. This is supported by the concussion consensus statement (CCS) which highlighted that digital objective approaches are crucial to improve the ability to diagnose and monitor SRC impairments [11,194]. Therefore, harnessing objective digital approaches like wearables, are key to advancing diagnostics and precision in mTBI/SRC assessment and monitoring.

Chapter 2 found that monitoring single isolated impairments is unlikely to drive any step changes into SRC assessment and diagnosis. Therefore, a necessary step change and progression in SRC assessment will require combining complementary multimodal technologies and moving away from reliance on the SCAT5 which collects data on isolated impairments. Through the first half of my thesis, I have provided a technical and clinical assessment of wearables for their propensity to capture objective data relevant to mTBI impairments. As further highlighted in chapter 2, collecting and integrating multimodal digital approaches (e.g., free-living gait) will likely augment and enhance data gathered from traditional methods. By understanding pragmatic challenges while addressing arising PoI's, I have understood the scope and range of opportunities afforded by wearables to devise a contemporary approach for mTBI assessment. Accordingly, the next chapter details a comprehensive process for a more rounded and thorough mTBI assessment.

6.3 **Free-living gait, next steps**

From the lessons learned, the latter stages of my thesis (chapters 8 to 10) will primarily apply and evaluate free-living gait in acute and chronic mTBI/SRC from free living data to gain better insights into player recovery and improved RTP. That exploration will be undertaken within the framework of investigating gait as a possible *diagnostic* (chapters 8 and 9) or *response* (bio) marker (chapter 10) [99]. But first, I describe a rigorous protocol for multimodal mTBI assessment for use within SRC.

Chapter 7: A protocol for multimodal mTBI assessment and management

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The journal article “*Wearables in rugby union: A protocol for multimodal digital sports-related concussion assessment*”, was published in **PLOS One** in 2021 (URL: <https://doi.org/10.1371/journal.pone.0261616>)

7.1 Introduction

To date, there has been no suggested use of digital technologies to capture novel biomarkers to better inform sports related mTBI (in low-resource settings). Accordingly, with evidence gathered from chapter 1 to chapter 5, I present a comprehensive and contemporary approach proposing use of attainable (and accessible) technologies for digital mTBI biomarker capture applicable in low resource settings (SRC context).

7.2 Progression to contemporary assessment

Non-invasive mobile wearable technologies have been used to objectively measure and monitor impairments in neurological injury [34,54]. Examples include visual assessment technologies to objectively monitor eye movements during laboratory tasks, assessing visual and cognitive processing [49,53]. In mobility assessment (e.g., balance, gait and turning), inertial wearables have successfully been used to track disease progression in Parkinson's disease [186]. Wearables offer several advantages over traditional (non-mobile) methods of assessment. This includes the opportunity for passive monitoring, whereby continuous data can be collected on participants without their active attention or participation. Remote monitoring outside of clinic or laboratory can augment traditional assessment and avoid 'snapshot' collection at episodic intervals [34,160]. Indeed, viewing SRC impairments in isolation could be futile and ignores the interconnected and related nature of SRC [20]. Wearables may provide continuous digital outcome measures, which can be easily compared and integrated with other impairments (e.g., cognitive function) [195]. SRC is considered a complex injury and will likely require a multimodal assessment approach to provide sufficient sensitivity for diagnosis and monitoring and enhanced understanding.

Using a multimodal approach with attainable wearables could provide objective and pragmatic outcomes from robust data to inform more insightful mTBI/SRC management [35,36]. However, to my knowledge, no multimodal protocol for this in rugby union has been published. As such I propose a comprehensive multimodal protocol to translate technical research into an attainable clinical application [81]. I suggest that multimodal digital-based wearables will yield more objective and insightful data in those with mTBI/SRC compared to the traditional assessment methods alone and the protocol proposed here will guide future data acquisition within my research and beyond. Throughout, useful estimates are provided to inform e.g., how long each assessment could take. It is my suggestion that this comprehensive protocol would enable future researchers to subsequently fine-tune their contemporary and digital data collection for mTBI assessments.

7.3 Methods

7.3.1 Study design

I designed this protocol around a repeated-measures observational study using a battery of SRC assessment tools (cognitive, visual motor, and symptom assessment). The protocol was developed according to the Standard Protocol Items: Recommendations for Interventional Trials' (SPIRIT) checklist-[196], as appropriate. As this is a study protocol no data has been included and was registered with clinicaltrials.gov (NCT04938570).

7.3.2 Participants

This protocol was designed pre-COVID-19 pandemic. At the time of writing University-level and amateur rugby players (males $n \approx 100$, and females $n \approx 100$) were to be recruited and assessed over one season. However, due to lockdown and social distancing, that was not conducted as part of this thesis. Accordingly, the following describes suggested approaches for a large observational approach.

Participants should be stratified according to gender (males and females). The inclusion and exclusion criteria are outlined in Table 10. Those that have a mTBI/Concussion during the season must have a diagnosis of mTBI from a healthcare professional (physiotherapist or medic) based upon

standard criteria or identified head injury from their contact sport governing body. Although the number of SRC that will be observed during the season is not known, we will compare number of head injuries/SRC to our results from cohort baseline testing. Those that do not sustain a concussion will also have follow up testing at the end of the season, which will allow comparison between baseline and post-season.

7.3.2.1 Setting

Testing will be conducted at Clinical Gait Laboratory, Coach Lane Campus, Northumbria University, Newcastle upon Tyne and at the amateur rugby clubs in the North East of England.

7.3.2.2 Recruitment

An ethics application was submitted to Northumbria University research ethics committee and approved June 2020 (23365). An amended ethics application (due to changes required from of the COVID-19 pandemic) was submitted to same ethics committee in October 2020 and approved in January 2021 but no participant recruitment remained largely prohibited until late 2022.

Upon resumption, written, informed consent to participate will be obtained by all participants prior to each stage of the study in accordance with General Data Protection Regulations (GDPR). All Northumbria University Rugby Union Players will be invited to take part in the study. Additionally, local adult rugby union teams within 25 miles of Newcastle Upon Tyne will be invited to participate. An advertisement will be sent via email to local rugby clubs and the university rugby teams. Those interested will then be given a Participant Information Sheet (PIS) and a letter concerning the study with consent form. Inclusion and exclusion criteria are detailed in Table 1. In brief, all participants must be ≥ 18 years, have minimal cognitive impairment (Short-Blessed test 0 and 8), have fluency in English. Those excluded from participating in the study include anyone with a medical history that could grossly impact balance; stroke, severe TBI, amputation, vestibular pathology, alcohol addiction or substance abuse.

Table 10. Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
<p>≥ 18 years;</p> <p>Have minimal cognitive impairment, defined as a score between 0 and 8 on the Short-Blessed test for cognitive function;</p> <p>English as a first language or fluency.</p> <p>Those that have a mTBI/Concussion during the season must have a diagnosis of mTBI from a healthcare professional (physiotherapist or medic) based upon standard criteria or identified head injury from contact sport.</p>	<p>Medical history of a neurological illness that could grossly affect balance or coordination (such as. stroke, greater than mild TBI, lower-extremity amputation, recent lower extremity or spine orthopaedic injury requiring a profile).</p> <p>Be a pregnant female</p> <p>Have past history of peripheral vestibular pathology or eye movement deficits.</p> <p>Be unable to abstain from medication/alcohol 24 hours in advance of testing</p>

7.3.2.3 Primary Outcomes

The primary outcomes of this study are the proportion of players who have altered free-living, quality-based gait/walking patterns (e.g., gait speed), defined as micro gait characteristics measured by a digital inertial sensor-based wearable. Secondary outcomes are related to the change in free-living turning characteristics and clinical based visual data. Possible predictors for altered free-living micro gait patterns will include baseline assessment and acute SRC timeframe.

7.3.2.4 Sample size calculation

The sample size calculation is based sample sizes from previous paper examining multimodal assessment, ~ 200 [80,195]. To determine the appropriate sample size (SS) for estimating the proportion of players we used the following formula as previously described.

$$SS = (Z\text{-score})^2 \times \text{proportion} \times (1 - \text{proportion}) / (\text{margin of error})^2$$

For a confidence level of 95%, α is 0.05 and the corresponding Z-value is 1.96. The sample proportion is unknown. We chose the number 0.50 (50%) because it takes the maximum spread into account. Consensus about the margin of error was achieved by joint discussion of the research group; a margin error of 0.075 (7.5%) was accepted. For a population size of 200 and a confidence level of 95%, α is 0.05 and the corresponding z-value is 1.96. Therefore, in total, 200 patients will be enrolled in the study to reach the necessary sample size.

7.3.2.5 Participant stratification

All participants (male \approx 100, female \approx 100) who respond to the advertisement will complete baseline testing during pre-season and post-season. In-house university assessment will allow a clear pathway for concussed university players to be referred for post-SRC assessment. Local and amateur players who responded to the initial advertisement and sustain a SRC during the season can a) self-refer themselves (player) or b) be referred with consent by other personnel (physiotherapist, clinician, coaches) into the study for testing. Testing availability for amateur players will be expanded (after 4:30pm Monday to Friday) to accommodate amateur player work/education commitments. Those diagnosed with SRC will be asked to attend a laboratory session with a subsequent free-living assessment at the following time frames post injury where possible; within 72 hours post, 7-14 days post, once returned to play and post season. The overall schedule and time commitment for trial participants is depicted in Fig 1. (A more generic flow diagram depicting the schedule is presented in supplementary material.)

TIMEPOINT**	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation			Close-out	
	$-t_1$	0	t_1 (baseline)	t_2 (within 72 hours)	t_3 (within 14 days)	t_4 (within 28 days or returned to play)	t_5 (post-season)
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
[List other procedures]	X						
Allocation		X					
INTERVENTIONS: NA							
ASSESSMENTS:			X	X	X	X	X
[baseline variables]			X				X
[Primary Outcomes]			X	X	X	X	X
[Secondary Outcomes]			X	X	X	X	X

Figure 1. SPIRIT diagram, overall schedule, and time commitment for trial participants

7.3.2.6 Anthropometric measures and screening

Test: Visual acuity (VA) eye chart and contrast sensitivity

VA is used to estimate degree of visual impairments in participants and will be measured binocularly using a standard eye chart. Participants will be asked to be seated or standing 4m from the chart. Participants will then be instructed to read aloud, starting from the top left, and moving down the chart. The test is terminated if the participant makes two consecutive errors. Assessment will be done for right and then left eyes.

Test: Height, weight and leg length.

Height (Bodysense Smart Scale, Eufy, USA) and weight (Seca 217, Seca Deutschland, Hamburg, Germany) will be measured for each participant. Participants leg length or sensor distance to ground will be measured [197], by a trained researcher/physiotherapist from posterior iliac spine to medial malleolus and used to inform inertial wearable algorithm analysis.

7.3.3 Data collection: In the lab

Test: Sports Concussion Assessment Tool 5th edition, SCAT5

Estimated time: (10-15 minutes)

The SCAT5 [11] is one of the most widely used assessment tools in aiding diagnosis and assessment measuring symptom scores [11], aspects of cognitive function (Standardised Assessment of Concussion [198] and balance function (modified balance error scoring system [199] via a pen and paper SCAT5 forms, Table 11.

Symptom: The test measures aspects of symptom score and severity recorded across 22 symptoms self-reported by the player. A higher score indicates a more severe or worsened symptom profile (out of 132).

Cognition: The standardised assessment of concussion, is a mental status assessment previously developed [198] but now incorporated in the SCAT5 assessing individuals across immediate memory, concentration and delayed recall and recorded via the SCAT5 form.

Balance: The modified Balance Error Scoring System (mBESS) test [199] is an assessment protocol used to assess impairments in SRC [79]. The mBESS test assesses balance, postural stability across six different positions (double leg stance, single-leg stance, tandem stance) and tandem gait walking over 2.5-3 meters). Participants will be asked to maintain eyes closed, with hands placed on the iliac crest for each test's duration (20 seconds). These tests are observed, and the number of errors counted. Errors are movements indicating a loss of balance or position such as; removing hands from iliac crest, stepping out with contralateral foot, stumbling or lifting forefoot or heel. The mBESS is assessed subjectively by the medical professional using a stopwatch and recorded using pen and paper. A higher error count indicating worse performance.

Table 11. Sports Concussion Assessment Tool, 5th version (SCAT5).

Assessment Domain	Component tests	Outcome Measures	Method of assessment
Symptom	Concussion Symptom Scale	Symptom severity (out of 22) Symptom total (out of 132)	Self-reported by player
Cognitive	Standardised Assessment of Concussion (SAC)	Orientation (out of 5) Immediate memory (out of 15 30) Concentration (out of 5) Delayed recall (out of 5 or 10)	Auditory/verbal assessment recorded on pen and paper
Neurological	Passive cervical movement	Pain (yes or no)	Subjectively assessed
	Finger nose test	Able to complete (yes or no)	Subjectively assessed
Visual	Horizontal Nystagmus	Double vision (yes or no)	Subjectively assessed
Balance	Tandem Gait	Able to complete (yes or no)	Subjectively assessed
	Modified Balance Error Scoring System (mBESS)	Total number of errors	Subjectively count number of errors

Test: Vestibular ocular motor screen (VOMS)

Estimated Time: (5-10 minutes)

The VOMS test includes a baseline measurement after which participants later verbally rate changes in headache, dizziness and nausea symptoms compared with their immediate baseline state on a scale from 0 (none) to 10 (severe) to determine if each of the tests provokes symptoms [51]. The test then measures impairments via this self-report across five sections (smooth pursuit, saccades, convergence, vestibular ocular reflex test and visual motion sensitivity test). Testing will be conducted on a standard height of chair (45cm) at a distance of 90-100cm away from the stimuli.

Test: Two-minute walk test

Estimated Time: (5-10 minutes)

Participants will be asked to complete two-minutes of continuous walking [177,178] at self-selected, normal walking speed over 8m with 180° turns, single and dual-task. Cognitive measurement to determine dual task will be conducted prior to any walking. The dual-task will involve the backwards digit span [200], which will be set to the maximal amount of numbers recalled in sitting. The first walking trial will be single task walking. Secondly for dual task, the participant will hear a series of numbers while walking and repeat the numbers in backwards order while walking. Participants will be instructed to concentrate on both tasks equally.

Test: High Level Mobility Assessment Tool, HiMAT

Estimated Time: (5-15 minutes)

HiMAT is a standardised outcome measure used to quantify motor performance in individuals with high-level balance and mobility deficits [201]. The HiMAT is scored over 13 items derived from expert clinicians' opinions and from existing multi-dimensional mobility scales. which includes tasks such as: backwards tandem walking, Walk over obstacle, Up/downstairs.

Table 12.Laboratory testing: Multimodal approach for SRC assessment

Assessment Domain	Test	Digital Approach	Digital Technology	Primary Outcome Measures	Time Commitment
Cognitive	Reaction Time	Computerised neurocognitive testing	Brain Gauge. Cortical Metrics, USA ¹	Reaction Time & reaction time variability (milliseconds)	10-15 minutes
	Amplitude Discrimination			Simultaneous and sequential amplitude discrimination (microns)	
Balance	SCAT 5 ⁵ (Modified Balance Error Scoring System)	Wearable Inertial Measurement Units	MoveMonitor, McRoberts, UK ²	Postural stability characteristics Sway (speed at which the centre-of-pressure moves) Root mean square (average variance signal captured) Jerk (the rate of change of acceleration from signal)	10-15 minutes
Gait & Turning	SCAT 5 ⁵ Lab: (Tandem Walk)	Wearable Inertial Measurement Units	MoveMonitor, McRoberts, UK ²	Gait characteristics Mean stance time (seconds, s) Mean step time (s) Mean stride time (s) Mean swing time (s) Mean stride length (cm) Mean stride velocity (cms-1) Turning characteristics Number of turns per hour (n) Turn Angle(°) Turn Duration(seconds) Turn Velocity (°/seconds)	10-15 minutes
	Lab: Two Minute Walk Test				
	High Level Mobility Assessment Tool (HiMAT)				
Visual	Horizontal Nystagmus test SCAT 5 ⁵	Mobile Eye Tracker	Pupil Labs, Core Eye Tracker, Germany ³ Tobii Pro Glasses 2 ⁴ (100Hz, Tobii Technology Inc., VA, USA)	Visual characteristics Mean and variability of fixations, saccades and smooth pursuit Symptom number	10 minutes
	Visual Oculomotor Screen				
Questionnaires	Neck Disability Index	Mobile application/secure questionnaire	PC or Tablet	Symptom Severity and symptom number	20-30 minutes
	Lower Extremity Function Scale			Symptom Severity and symptom number	
	International Physical Activity Questionnaire			Self-reported activity levels	
	Dizziness Handicap Inventory			Symptom Severity and symptom number	
	Neurosymptom Inventory Index			Symptom Severity and symptom number	

¹ <https://www.corticalmetrics.com/>

² <https://www.mcroberts.nl/products/movemonitor/>

³ <https://pupil-labs.com/products/core/>

⁴ <https://www.tobii.com/product-listing/tobii-pro-glasses-2/>

⁵ <https://bjsm.bmj.com/content/bjsports/early/2017/04/26/bjsports-2017-097506SCAT5.full.pdf>

7.3.4 Digital technologies

Using traditional approaches but overlaid with digital technologies to provide more objective and insightful outcome measures.

7.3.4.1 Digital neurocognitive tests

Conducted with the Brain Gauge Pro². Cortical Metrics, Chapel Hill, NC, USA. Testing takes approximately 8 minutes and is completed with participants sitting at a laptop [202,203]. Two computer mouse probes on the device provide a stimulus through vibration (25-50Hz) for participants index (D2) and third (D3) fingers. Participants are asked to respond by pressing their D2 and D3 according to specific tests. Outcomes calculated by the technology are reaction time (RT) measured in milliseconds, sequential, simultaneous amplitude discrimination (measured in microns) and reaction time variability.

7.3.4.2 Wearable eye-tracking

Conducted with the wearable eye tracker (Pupil Labs³, Core Eye Tracker, Berlin, Germany. 160×51mm, high speed 120hz and 200hz) and Tobii Pro Glasses 2³ (100Hz, Tobii Technology Inc., VA, USA) which have shown to have good accuracy and showed the least error accuracy error overall in comparison with three other models of wearable eye-trackers [204]. The wearable eye-tracker in this protocol will be compared to a subjective test (VOMS), which has been clinically adopted in neurological assessment and will be used a reference standard [51,205,206].

7.3.4.3 Inertial wearable

The AX6 and/or MoveMonitor (McRoberts, Netherlands⁴; 106.6×58×11.5mm, 55g) comprises an accelerometer (+/- 100Hz) and gyroscope (+/- 8g) tri-axial sensors and are worn on L5, attached with an elastic strap. The latter wearable has been used extensively for functional and mobility monitoring in neurological disorders and is considered a valid technology which can capture data in controlled/lab/clinic and free-living environments [207–210]. The MoveMonitor technology uses the same hardware as the AX6 but can be attached using the provided Velcro waist belt, allowing easy attachment/removal and may help overcome the limitation of using tape to fix as with the AX6 used in chapter 5. This will be used to compare against traditional methods of gait assessment in walking tasks (lab and free-living assessment, see chapter 6).

7.3.5 Instrumentation with digital technologies

7.3.5.1 VOMS and eye tracking

Due to the test's subjective outcomes (provocation of non-specific symptoms), the VOMS cannot be used in isolation to diagnose SRC. Wearable eye trackers may provide an objective method of instrumenting traditional subjective tests like the VOMS and yield enhanced metrics on fixations, saccades and smooth pursuit [50,211]. We will use the Pupil Labs, Core eye tracker or Tobii Pro Glasses 2 while comparing the traditional VOMS test results across three main movements, fixations, saccades and smooth pursuits. Data is wirelessly transferred to Pupil Labs/Tobi proprietary software and stored locally. Data will then be stored on a secure Further analysis of these will be made using a custom-made MATLAB[®] (MathWorks Inc, Massachusetts, USA) algorithm as previously described [205,212].

7.3.5.2 Balance, two-minute walk test (gait and turning)

By instrumented digital approaches such as use of inertial sensor-based wearables, detection of subtle deficits may be detected. Indeed, the instrumentation of the balance error scoring system (BESS) has been shown to have superior diagnostic classification compared to traditional balance tests in concussion/mTBI [78]. Data will be downloaded to PC or laptop via USB and uploaded to a secure database or file storage and analysed. Movement bouts will be calculated for lab and free-living balance,

² <https://www.corticalmetrics.com/>

³ <https://pupil-labs.com/products/core/>

³ <https://www.tobii.com/product-listing/tobii-pro-glasses-2/>

⁴ <https://www.mcroborts.nl/products/movemonitor/>

gait and turning characteristics using bespoke MATLAB® algorithms [86,153]. Free-living data will be initially processed using two separate custom-made and validated MATLAB® algorithms to estimate free-living balance (e.g., jerk, sway), gait (e.g., mean step time, stance time variability) and turning (e.g., peak velocity, turn duration) characteristics [132,153,213,214].

Differences in gait between single and dual task will be examined rather than dual task cost. Absolute dual-task differences between groups (healthy vs those with a mTBI) will be examined to investigate if objectively measured dual-task walking could be a useful assessment for SRC, which will be compared to the use of single-task gait outcomes.

7.3.6 Data collection: Beyond the lab

At present wearable laboratory-based motor assessment in SRC only offers a snapshot assessment. Little research has focused on participants motor assessment outside of the laboratory at episodic intervals of assessment. To overcome this limitation, testing could be better utilised through constant remote evaluation in free-living environments. This would mitigate the need for the clinician to be present and would allow a higher frequency of testing within the player's own environment [89]. Although testing in the latter would be conducted in less controlled conditions, there is considerable value in conducting testing in remote, real-world/free-living as s/he would be within habitual conditions [34,90,91].

7.3.6.1 Test: Free-living gait

After laboratory testing participants will wear the MoveMonitor (L5) continuously for 7-days (weekdays and weekend to examine daily habitual fluctuations). Participants will be instructed how to take off and reattach the device for general hygiene purposes and return the device at their next laboratory visit. Free-living balance, gait and turning data will be segmented from raw (sample level) data and analysed to generate clinically relevant spatial and temporal outcomes to examine habitual motor and behavioural characteristics as previously described, Table 4 [86,153]. Application and evaluation of conceptual models previously described [91,95,97] will be applied to provide better insight to habitual player recovery, which may better inform RTP.

Table 13. Data collection: beyond the lab

Assessment Domain	Digital Approach	Digital Technology	Primary Outcome Measures		Time
Balance, gait & turning	Wearable Inertial Measurement Units	MoveMonitor1, McRoberts, UK	Balance Root mean square (m/s ²), Jerk (m ² /s ⁵), Sway (area, mm ² /s ⁵) Gait Mean stance time (seconds, s) Mean step time (s) Mean stride time (s) Mean swing time (s) Mean stride length (cm)	Turning Number of turns per hour (n) Turn Angle (°) Turn Duration (seconds) Turn Velocity (°/seconds)	Up to 7 days
Symptom (SCAT 52 Symptom)	Mobile application/Secure questionnaire	PC or Tablet	Symptom severity (out of 22) Symptom total (out of 132)		5-10 minutes

¹<https://www.mcroberts.nl/products/movemonitor/>

²SCAT5: Sports Concussion Assessment Tool 5

7.3.6.2 Test: Concussion symptom checklist, SCAT5

Technology: Secure questionnaire

Participants will complete symptom assessment during their RTP, via a secure mobile application or questionnaire. This will be from the concussion symptom scale as part of the SCAT5 [11].

7.3.7 Digital outcomes (primary)

7.3.7.1 Cognitive characteristics

Reaction time tests how quickly participants can respond to stimuli. Reaction time variability is a measure of how quickly participants fatigue or concentrate [202,203]. Amplitude discrimination tests how well participants brain can differentiate between similar stimuli. These will be tested across all participants and tracked across different time points of recovery.

7.3.7.2 Gait outcomes

The inertial balance, gait and turning characteristics will be estimations from the MoveMonitor. The balance (postural control tasks, BESS) includes root mean square (m/s^2), (root mean square of signal), Jerk (m^2/s^5), (first derivative of acceleration signal) and Sway (area, mm^2/s^5). Gait characteristics include step time (s), stride time (s), swing time (s), stance time (s), step length (m), step velocity (ms^{-1}). Those comprehensive gait measures will be assess upon division into four original domains (pace, rhythm, variability and turning) based on the previously described model [95]. Turning characteristics include number of turns per hour (n), turn angle ($^{\circ}$), turn duration (s) and turn velocity ($^{\circ}/s$), Table 13.

7.3.8 Secondary Subjective outcomes

7.3.8.1 Visual Characteristics

As outlined in the visual oculomotor screening test, we will be comparing traditional VOMS versus the eye-trackers calculations for:-(1) smooth pursuit, (2) horizontal and vertical saccades, (3) near point of convergence (NPC) distance, (4) horizontal vestibular ocular reflex (VOR), and (5) visual motion sensitivity (VMS) from the visual oculomotor screen.

7.3.8.2 Questionnaire #1: Neck Disability Index

Estimated Time: (5minutes)

The Neck Disability Index (NDI) is a patient recorded functional status questionnaire [215] with 10 items (pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation). The NDI a commonly used self-reporting measure for neck pain which will be monitored across the study. This will be given to participants at each testing session and used to compare specific neck pain responses from baseline SRC.

7.3.8.3 Questionnaire #2: Lower Extremity Function Scale

Estimated Time: (5minutes)

The lower extremity functional scale (LEFS) is a questionnaire containing 20 questions about a person's ability to perform everyday tasks [216]. Clinicians can use the LEFS as a measure of patients' initial function, ongoing progress and outcome, as well as to set functional goals. The LEFS can be used to evaluate the functional impairment of a patient with a disorder of one or both lower extremities and can be used to monitor the patient injuries progress over time. This will be used to account for injuries that may negatively impact gait and influence any changes measured.

7.3.8.4 Questionnaire #3 Dizziness Handicap Inventory

The dizziness handicap inventory (DHI) is a 25 item self-report questionnaire designed to assess perceived dizziness affecting function [217]. The DHI will be used as secondary outcomes and compared between healthy and SRC individuals.

7.3.8.5 Questionnaire #4 Neurosymptom Inventory Index

The Neurobehavioral Symptom Inventory (NSI) is a self-reported evaluation tool [218] frequently completed after mTBI. This will be used to monitor and measure post-concussion symptom changes between healthy and non-concussed individuals.

7.3.9 Statistical analysis

This is an exploratory study consisting of two groups. To the authors knowledge, there has yet to be a comprehensive free-living analysis of participants with SRC in rugby union. However, there have been analyses of non-sporting concussion/mTBI. Previous non-sporting studies have used datasets of 30-100 individuals [86]. Therefore, our original anticipated dataset size of ~200 individuals, will provide greater statistical power to quantify between-group differences and detect small differences in visual, motor and symptom metrics. The multimodal battery of assessment used in this study will compare metrics between wearable systems and against traditional assessment methods. Data will be analysed in SPSS (v23, IBM) and R studio (R. RStudio, Boston, MA, USA). All data will be checked for normality distributed with Shapiro-Wilks tests before conducting parametric tests. Independent t-tests will be performed comparing demographic information between groups. Anonymised data will be made available on reasonable request.

7.3.9.1 Primary analyses

The study aims will be explored with the analysis below.

1) Investigate use of multimodal digital-based wearables to capture objective data relevant to cognitive, gait and visual metrics in those with SRC compared to a traditional assessment method.

For the purposes of this thesis, paired sample t-tests will be used to assess differences in group means for laboratory-based gait (two-minute walk test, single and dual-task) and visual (VOMS) between healthy and SRC groups. To examine differences in SRC laboratory and free-living mobility across multiple recovery time points. To determine which features of each assessment domain (visual, motor, symptom) is best to distinguish SRC from healthy we will use receiver operating characteristic (ROC) and area under the curve (AUC). Later work should also investigate balance and turning outcomes and balance assessment (mBESS, HiMAT) but is beyond the scope of this thesis.

2) Investigate free-living mobility/gait in those with SRC

Between groups (concussed or non-concussed) differences in macro/micro gait and turning characteristics will be analysed with covariance (gender and age) for pre- and post-season, free-living motor assessment. and linear mixed models to further examine concussed player time-points and recovery.

3) Consider practical and technical considerations of digital multimodal protocols in SRC.

Feedback will be collected from participants on usability of wearables during laboratory and free-living assessment using the system usability scale [219]. A higher score is associated with improved usability and anything over 68 above average [219]. This will be analysed and compared across groups.

7.3.9.2 Secondary analyses

1) Explore the interaction and sex differences between all outcomes

We will use Pearson's correlation analysis heatmap to explore the relationship between mobility, visual and self-reported symptoms in mTBI/SRC and across sex. Thus, this component of the interaction analysis will be data-driven, rather than hypothesis-driven. Statistical significance will be determined at $p < 0.05$ unless otherwise stated. Principal Component Analysis and/or Receiver Operating Characteristics will be used to compare those with SRC history and no SRC concussion history across cognitive, visual and motor impairments. This will be used to assess/ deduce distinct groupings or clustering or the most useful of the various cognitive, visual, and motor characteristics.

7.4 Discussion

Here we provide a protocol for multimodal objective SRC assessment, with a focus on wearable technologies. At present there is no gold standard or proposed method for SRC assessment, currently impairments are often viewed in isolation and not interconnected. This protocol will allow consideration of the combined and interactive impact of SRC on gait, cognition and vision and symptom recognition using wearables to collect objective data in university rugby union. This multimodal assessment paradigm distinguishes therefore itself from other work in the field. To my knowledge, no research has examined free-living gait in SRC among university rugby players. Furthermore, there hasn't been attempts to explore visual and motor impairments concurrently in laboratory and free-living environments. Therefore, the development and synthesis of this multimodal protocol would provide an important step in quantitatively monitoring SRC motor and visual impairments and begin preliminary analyses of multimodal assessment in SRC.

This protocol does carry some limitations. Firstly, there are several equivalent technologies that could be deployed or tested across each component test (cognitive, motor and visual). However, given the lack of multimodal protocols in SRC, we feel the proposed manuscript provides a starting point to work on and develop in future research. Secondly, although we aim to have participants with SRC assessed within 72 hours of injury and associated time points, this may not be feasible in all cases and players may not wish to be tested in this frequency. Likewise follow up once returned to play, may not be always feasible if there are chronic issues associated with return to play and extended time lapse post injury or issues associated with local lockdowns due to COVID-19. These limitations and solutions may become apparent when practically tested.

7.5 Conclusion

Current SRC assessment focusses on impairments viewed in isolation, ignoring the interconnected nature and spectrum of SRC. As such, reliance on traditional methods of assessment and monitoring in SRC is limiting our understanding. Multimodal digital technologies can measure and monitor impairments non-invasively more informed assessments [34] in neurological injury [54].

My suggested multimodal and digital approach could yield a more objective and robust health profile for those who sustain a mTBI/SRC. Additionally, with an increased frequency of testing, a greater insight into SRC progression and recovery may be possible. This combination of data (cognitive, gait and visual assessment) may uncover mechanistic interactions, showing trends between different impairments to infer new recovery patterns. Here my proposed multimodal protocol for digital assessment, could be used in conjunction and enhance the current SCAT5 approach which may provide an important first step towards clinical deployment.

In the next chapter, I use a portion of my protocol among a baseline cohort of athletes with and without a recent mTBI/SRC to investigate the primary analysis presented here (section 7.3.8.1). This is set within a single season with analysis of players having acute mTBI/SRC. The aim is to explore instrumented free-living gait as a diagnostic (bio) marker.

Chapter 8: mTBI assessment: A focus on gait as a diagnostic marker

This chapter is developed from an abstract previously presented to fit the context of this thesis. The article “*Exploring digital sports related concussion (SRC) assessment, performed by a single clinician*”, was presented at the sixth edition of the **International Consensus Conference on Concussion in Sport** in 2022, Amsterdam, The Netherlands. The abstract will be published online in a special themed issue of the **British Journal of Sports Medicine**, 2022.

8.1 Introduction

In this chapter I use a portion of my protocol to explore gait as a diagnostic (bio) marker (with wider multimodal measures) to assess sensitivity distinguishing those with mTBI/SRC history and none [99]. This chapter also explores the practicalities and feasibility of conducting large scale multimodal assessment in the same cohort pertaining to adherence. (Note: From the onset of my doctoral studies and protocol description, this study initially targeted a large cohort of approx. 200 players but had to be curtailed and conducted due to the impact of COVID-19.)

8.2 Background

Relying on pen and paper tests is limiting the opportunity for robust data analysis which may hinder understanding of the interconnected nature and relationships in deficit recovery. In chapters 4 and 5 I showed that digital approaches provide more objectivity to measure and monitor impairments in SRC. However, to my knowledge, no multimodal protocols with remote free-living gait assessment mTBI/SRC across rugby union have been tested. As such there was opportunity and strong rationale for implementing and testing the use of digital multimodal approaches in their capacity as objective tools in SRC assessment/monitoring. From chapter 7, there is a need to practically test, develop and refine multimodal protocols which may augment and support traditional methods (SCAT5) [81]. Moreover, a gap remains as to whether measures of free-living gait quality are useful in distinguishing those with recent SRC history and those without. Here I investigate results from a multimodal assessment of university athletes, my aims were to; Therefore, a gap remains as to whether measures of free-living gait quality are useful in distinguishing those with recent SRC history and those without. Here I conduct the primary analysis outlined in the previous chapter (section 7.3.8.1). Accordingly, my broad aims of this chapter/study were to;

1. Investigate use of multimodal digital-based wearables to capture objective data relevant to cognitive, gait and visual metrics in those with SRC compared to a traditional assessment method.
2. Explore free-living gait as a plausible diagnostic (bio) marker.
3. Consider practical and technical considerations of digital multimodal protocols in SRC.

8.3 Methods

8.3.1 Participants

Fifty/50 male university rugby union athletes, 30 with a previous SRC history (pSRC), 20 with no previous SRC (npSRC) were enrolled in the northeast of England and underwent a baseline multimodal battery of assessment, performed by one clinician. During the season, 8 of these players (from pSRC) were diagnosed with acute SRC (aSRC) within the first 2 months of the season starting (40.38 ± 20.34 days) by the university physiotherapist based on standard SCAT5 criteria. The athletes spanned a range of playing positions, Table 15. Five of each group (aSRC and npSRC) were followed up at the end of the season (post season) for free-living gait assessment only, Figure 12. Inclusion criteria and exclusion criteria were consistent as previously described in chapter 7. (Ethics approval and approaches to consent previously described in chapter 5.)

8.3.2 Assessments

Participants underwent a multimodal assessment battery of assessment including symptom, visual, motor, and cognitive assessment and remote gait assessment during pre-season testing Northumbria University campus facilities and laboratories. The total supervised assessment within the clinic took approximately 45 minutes and the remote gait assessment was for ~7 days.

All participants with SRC history (pSRC, within last 12 months) were self-reported by the individual and with consent of participants verified against university medical records to ensure

accuracy. Those included as acute SRC (aSRC, within 28 days or 1 month) were initially assessed (within 7 days) and diagnosed by a university physiotherapist and researcher using SCAT5 [11]. All novel (non-SCAT5) assessment approaches were used ‘non-operational’ (blind). This means the team and or medical staff were abided to not to look at results or allow findings to influence RTP decisions as previously described [48,220].

8.3.2.1 Reference standard test (SCAT5)

The primary outcomes of this study were traditional; (SCAT5) symptom number and severity, orientation, immediate memory, balance errors and delayed recall.

8.3.3 Multimodal assessments (Lab)

The experimental multimodal assessment protocol incorporated a number of domains including cognitive, gait, visual and questionnaires symptom inventories; (Becks Depression Score, Lower extremity function scale, Neurobehavioral Symptom Inventory) Cognitive (Simple Reaction Tim, milliseconds). Visual; Visual Oculomotor score. Motor; 3m tandem walk time (seconds) which can be found in detail in Table 14.

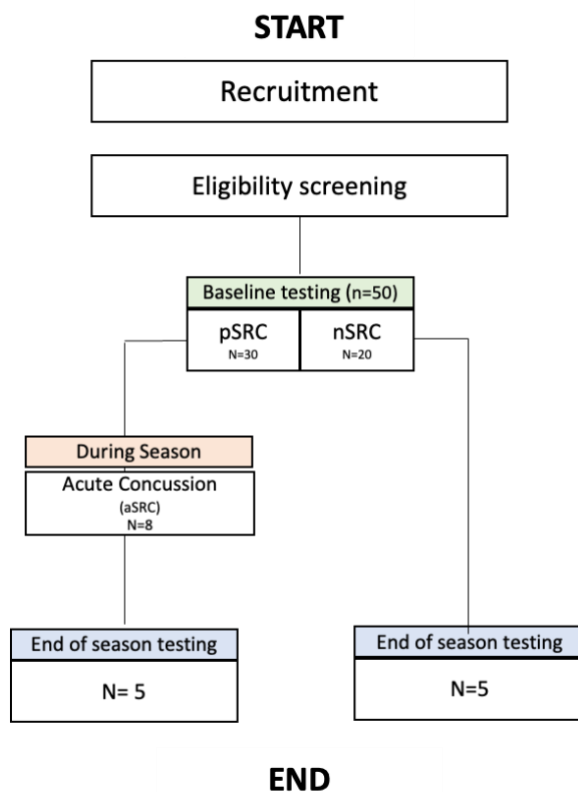


Figure 12.Schematic of testing

Table 14. Multimodal assessment

Assessment Domain	Test	Digital Approach	Digital Technology	Primary Outcome Measures	Time Commitment
Physiological	Vital sign	Pulse oximetry (spectrophotometric methodology)	Finger pulse oximeter	Resting heart rate (beats per minute) Oxygen Saturation (percentage %)	1-2 minutes
Symptom	Neck Disability Index	Secure questionnaire	PC or Tablet	Symptom Severity and symptom number	20-30 minutes
	Lower Extremity Function Scale				
	Dizziness Handicap Inventory				
	Neurosymptom Inventory Index				
Visual	Horizontal Nystagmus test SCAT 5 ³	Secure questionnaire	PC or Tablet	Visual characteristics Smooth Pursuit (out of 10) Horizontal Saccade (out of 10) Vertical saccade (out of 10) Convergence (out of 10) Convergence distance (centimeters,cm) VOR horizontal (out of 10) VOR vertical (out of 10) VMS total symptom (out of 10)	10 minutes
Cognitive	Reaction Time	Computerised neurocognitive testing	Brain Gauge. Cortical Metrics, USA ¹	Reaction Time & reaction time variability (milliseconds)	10-15 minutes
	Amplitude Discrimination			Simultaneous and sequential amplitude discrimination (microns)	
Gait	SCAT 5 ³ Lab: (Tandem Walk)	Wearable Inertial Measurement Units	MoveMonitor, McRoberts, UK ²	Time to complete (seconds) Mean stance time (seconds, s) Mean step time (s) Mean stride time (s) Mean swing time (s) Mean stride length (cm) Mean stride velocity (cms-1)	10-15 minutes in lab and 7 days free-living
	Lab: Two Minute Walk Test				
	Free-living				

¹ <https://www.corticalmetrics.com/>

² <https://www.mcroberts.nl/products/movemonitor/>

³ <https://bjsm.bmj.com/content/bjsports/early/2017/04/26/bjsports-2017-097506SCAT5.full.pdf>

8.3.3.1 Instrumented gait: lab and free-living

Gait was assessed in the lab and free-living (Table 14) by an inertial sensor-based wearable worn on the lumbar spine (MoveMonitor, McRoberts, Netherlands; 106.6×58×11.5mm, 55g). Participants wore the IMU around their waist for as much time as possible for up to 7 days using the protocol described previously, Chapter 7 [220], [221]. Data were stored on the MoveMonitor IMU internal storage (8GB) and then downloaded to a laptop. Free-living data were then processed using custom-made and validated MATLAB® (MathWorks Inc, Massachusetts, USA) algorithms to estimate 6 free-living gait quality metrics [132,153,213,214].

Laboratory and free-living measures of gait quality were calculated using a bespoke MATLAB® algorithm as detailed in chapter 2. In brief, the waist worn IMU was used to examine orientation and periods of static and dynamic activity [132,153]. Subsequently, the latter were examined for initial and final foot contact events within the gait cycle via the continuous wavelet transform [145], where a bout/period of walking was predefined by a time period of between 0.25 and 2.25 seconds and ≥3 steps [118]. For the purposes of this study a bout of gait ≥2 minutes were used only. This provides continuity

from chapters 4 and 5, and comparison to traditional tasks. Gait characteristics included mean; stance time (seconds, s), step time(s), stride time (s), swing time (s), stride length (meters, m) and stride velocity (meters per second, ms^{-1}).

8.3.4 Statistical analyses

Data were analysed in SPSS (v23, IBM) and R studio (Boston, MA, USA). All data were normally distributed as assessed with Shapiro-Wilks tests and therefore parametric tests were used. Independent t-tests were performed comparing demographic information between those with SRC and those without.

To estimate which gait characteristic differentiated mTBI/SRC history patients from those with no SRC history, I used ROC and AUC analysis. ROC analysis provides a trade-off between specificity and sensitivity between the various laboratory and free-living gait quality metrics and binary classification of either pSRC, and npSRC and aSRC. Statistical significance was determined at $p < 0.05$ (two-tailed) unless otherwise stated. Bonferroni corrected significance values were applied for multiple comparisons ($p < 0.002$) where applicable. Effect sizes were interpreted as small (0.2), medium (0.5), and large (0.8) as previously described [222].

Table 15. Group characteristics

Variable	Baseline		During Season
	npSRC (n =20) Mean ± S.D	(pSRC) (n= 30) Mean ± S.D	aSRC (n= 8) Mean ± S.D
Age (years)	22.58 (4.84)	21.62 (5.58)	21.17 (1.04)
Height (cm)	182.40 (6.8)	181.57 (6.5)	180.38 (4.77)
Mass (kg)	91.88 (11.4)	92.94 (11.64)	95.48 (7.36)
Number of previous concussions	-	2 (1)	2.13 (1)
Days Since last Injury ^a (n)	-	365 (328)	5.75 (2.95)
Return to Play from last injury (days)	-	24.21 (6.8)	25.63 (8.05)
Position: Forward (F), Back (Bk)	F (9), Bk (11)	F (16), Bk (14)	F (5), Bk(3)

8.4 Results

8.4.1 Wearer adherence and practical considerations

Wearer adherence analysis and results from the system usability scale (section 7.3.8.1) show that there was mixed user experience and usage among the cohorts. The number of days worn is low, but consistent across the cohorts and no significant differences between those with baseline and aSRC groups, Table 16.

8.4.2 SCAT5

A higher SCAT5 symptom scores indicates a worse performance. My results show that the SCAT5 (section 7.3.3) did not show any significant differences ($p > 0.05$) between those with pSRC and npSRC at baseline (Table 17) with both scoring low, indicating a better performance. Comparing those npSRC to aSRC there were significant differences for symptom severity ($p = 0.01$). Many variables were classified as small (0.2) or medium (0.5) with only one variable symptom severity classified as a large effect size (1.1).

8.4.3 Supervised assessment

There were significant differences between groups (pSRC vs npSRC) in cognitive and laboratory gait assessment. Interestingly reaction time and reaction time variability was higher in the pSRC cohort ($252.98s \pm 39.56$) than aSRC ($236.09s \pm 40.08$) with the equivalent trend for reaction time variability (Table 17). Interestingly subjective gait outcomes, 3-meter tandem gait was significantly different between groups pSRC and nSRC with those with a recent SRC history ($15.90s \pm 3.97$), walking much slower than those without ($13.37s \pm 4.37$). In contrast there were no significant differences between groups for the pairwise comparison of pairwise comparison nSRC vs aSRC ($p < 0.05$). There were also no significant differences between groups for physiological measures across all groups (Table 17).

8.4.4 *Remote assessment*

Free-living gait (Table 19) in baseline cohorts which showed pSRC and aSRC had higher mean step velocity (ms^{-1}) than npSRC. This contrasts to laboratory assessment which found pSRC had significantly lower mean step velocity than npSRC, respectively.

Table 16: Wearer adherence and system usability scales across cohorts

Qualitative metric	Baseline		During Season	Pairwise comparison <i>npSRC vs pSRC</i>			Pairwise comparison <i>npSRC vs aSRC</i>		
	npSRC (n=20) <i>Mean ± S.D</i>	pSRC (n=30) <i>Mean ± S.D</i>	aSRC (n= 8) <i>Mean ± S.D</i>	<i>F</i>	<i>sig</i>	η_p^2	<i>F</i>	<i>sig</i>	η_p^2
Number of days worn (<i>n</i>) ⁱⁱ	3.85 ± 1.98	4.55 ± 1.98	4.25 ± 2.19	0.22	0.29	0.35	0.15	0.64	0.63
Percentage of day worn (%) ⁱⁱ	23.9 ± 18	28.93 ± 18.47	20.63 ± 14.45	0.12	0.35	0.28	0.22	0.66	0.19
System Usability Scale (<i>out of 100</i>) ⁱⁱ	45 ± 7.25	45.33 ± 8.88	46.88 ± 9.14	0.16	0.89	0.04	0.48	0.57	0.24

ⁱA lower score is better
ⁱⁱA higher score is better

Table 17: SCAT5 in baseline groups and acute

SCAT5 Variable	Baseline		During Season	Pairwise comparison <i>npSRC vs pSRC history</i>			Pairwise comparison <i>npSRC vs aSRC</i>		
	<i>npSRC</i> (n=20) <i>Mean ± S.D</i>	<i>pSRC</i> (n=30) <i>Mean ± S.D</i>	<i>aSRC</i> (n= 8) <i>Mean ± S.D</i>	<i>F</i>	<i>sig</i>	η_p^2	<i>F</i>	<i>sig</i>	η_p^2
Symptom Number (<i>out of 22</i>) ⁱ	0.00 ± 0.00	0.20 ± 0.81	0.88 ± 2.48	5.49	0.23	0.32	14.4	0.1	0.68
Symptom Severity (<i>out of 132</i>) ⁱ	0.65 ± 2.5	1.07 ± 3.39	7.13 ± 10.52	0.66	0.64	0.14	38.7	0.01*	1.1
Orientation (<i>out of 5</i>) ⁱⁱ	4.85 ± 0.34	4.90 ± 0.31	4.63 ± 0.52	1.09	0.60	0.15	4.97	0.20	0.55
Immediate Memory (<i>out of 15</i>) ⁱⁱ	12.25 ± 3.58	11.73 ± 3.4	13.38 ± 1.4	0.03	0.61	0.15	1.45	0.40	0.36
Balance Errors (<i>out of 30</i>) ⁱ	6.70 ± 1.72	6.37 ± 3.011	7.38 ± 2.07	7.23	0.66	0.13	0.85	0.38	0.37
Delayed Recall (<i>out of 5</i>) ⁱⁱ	3.16 ± 1.61	3.00 ± 1.59	3.50 ± 1.41	0.02	0.74	0.1	0.40	0.61	0.22

ⁱA lower score is better
ⁱⁱA higher score is better

Table 18. Supervised assessment of baseline and acute groups

Assessment Domain	Variable	Baseline		During Season	Pairwise comparison npSRC vs pSRC history			Pairwise comparison npSRC history vs aSRC		
		npSRC (n=20) Mean ± S.D	pSRC (n=30) Mean ± S.D	aSRC (n=8) Mean ± S.D	F	sig	d	F	sig	d
Physiological	Resting Heart Rate (beats per minute) ⁱ	73.10 ± 10.32	72.70 ± 11.40	81.57	0.02	0.90	0.04	0.00	0.07	0.83
	Oxygen Saturation (percentage %) ⁱⁱ	97.65 ± 1.84	97.70 ± 1.10	98.29 ± 0.49	0.06	0.90	0.04	0.45	0.38	0.39
Symptom	Becks Depression Inventory (out of 63) ⁱ	1.68 ± 3.22	4.23 ± 8.66	5 ± 7.82	3.02	0.23	0.36	5.65	0.13	0.67
	Lower Extremity Function Scale (out of 80) ⁱⁱ	62.09 ± 33.68	64.09 ± 30.92	53 ± 41.1	0.17	0.19	0.06	0.99	0.61	0.25
	Neurobehavioral Symptom Inventory (out of 88) ⁱ	2.63 ± 5.79	6.42 ± 16.39	5.6 ± 7	1.81	0.34	0.28	0.24	0.3	0.48
	Neck Disability Index (out of 50) ⁱ	1.37 ± 2.17	2.23 ± 3.97	1.50 ± 2.5	1.73	0.39	0.25	0.06	0.89	0.06
Visual Visual Oculomotor Screen (VOMS)	Smooth Pursuit (out of 10) ⁱ	0.00 ± 0.00	0.04 ± 0.20	0.00 ± 0.00	2.89	0.42	0.26	-	-	-
	Horizontal Saccade (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-
	Vertical saccade (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-
	Convergence (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-
	Convergence distance (centimeters,cm) ⁱ	4.31 ± 2.2	5.12 ± 2.91	4.6 ± 1.83	1.34	0.36	0.31	0.01	0.75	0.17
	VOR horizontal (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-
	VOR vertical (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-
VMS total symptom (out of 10) ⁱ	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	-	-	-	-	-	-	
Cognitive (BrainGauge)	Reaction Time (milliseconds) ⁱ	252.98 ± 39.56	236.09 ± 40.08	258.83 ± 49.3	0.30	0.02*	0.42	2.66	0.34	0.41
	Reaction Time Variability (milliseconds) ⁱ	22.82 ± 18.15	15.96 ± 7.87	22.49 ± 11.5	10.63	0.01*	0.5	0.07	0.89	0.06
	Simultaneous Amplitude Discrimination (microns) ⁱ	68.59 ± 25.95	78.06 ± 39.48	107.5 ± 47.64	3.35	0.27	0.28	4.76	0.07	0.78
	Sequential Amplitude Discrimination (microns) ⁱ	54.76 ± 33.81	67.38 ± 30.15	68.8 ± 43.31	0.43	0.12	0.40	4.87	0.31	0.44

ⁱA lower score is better

ⁱⁱA higher score is better

Table 19. Supervised and free-living gait of baseline and acute groups

Assessment Domain		Variable	Baseline		During Season	Pairwise comparison <i>npSRC vs pSRC</i>			Pairwise comparison <i>npSRC history (B) vs aSRC</i>		
			<i>npSRC</i> (<i>n</i> =20) Mean ± S.D	<i>pSRC</i> (<i>n</i> =30) Mean ± S.D	<i>aSRC</i> (<i>n</i> =8) Mean ± S.D	<i>F</i>	<i>sig</i>	<i>d</i>	<i>F</i>	<i>sig</i>	<i>d</i>
Subjective Clinical Outcomes		3-meter tandem gait (<i>seconds</i>) ⁱ	15.90 ± 3.97	13.37 ± 4.37	16.25 ± 5.23	0.04	0.04*	0.60	3.59	0.86	0.07
		2-minute walk test distance Single (<i>meters</i>) ⁱⁱ	127.70 ± 17.66	132.73 ± 26.59	127.75 ± 17.65	3.1	0.46	0.22	0.34	0.99	0.03
		2-minute walk test distance Dual (<i>meters</i>) ⁱⁱ	124.50 ± 16.23	129.60 ± 24.43	129 ± 17.63	2.92	0.42	0.24	0.07	0.52	0.27
Wearable Laboratory Gait	2-minute walk test distance (Single)	Mean stance time (<i>seconds, s</i>)	0.70 ± 0.07	0.71 ± 0.06	0.72 ± 0.52	0.49	0.78	0.09	0.02	0.82	0.1
		Mean step time (<i>s</i>)	0.56 ± 0.07	0.56 ± 0.46	0.55 ± 0.51	0.99	0.81	0.08	0.42	0.66	0.19
		Mean stride time (<i>s</i>)	1.11 ± 0.10	1.11 ± 0.83	1.09 ± 0.13	0.15	0.78	0.09	0.59	0.61	0.26
		Mean swing time (<i>s</i>)	0.41 ± 0.06	0.41 ± 0.06	0.39 ± 0.68	1.5	0.9	0.04	0.68	0.59	0.23
		Mean step length (<i>meters, m</i>)	0.65 ± 0.07	0.61 ± 0.09	0.66 ± 0.33	3.73	0.07	0.56	3.83	0.16	0.62
		Mean step velocity (<i>ms⁻¹</i>)	1.17 ± 0.10	1.04 ± 0.27	1.2 ± 0.7	19.17	0.02*	0.72	8.13	0.11	0.72
	2-minute walk test distance (Dual)	Mean stance time (<i>seconds, s</i>)	0.70 ± 0.10	0.71 ± 0.07	0.68 ± 0.13	0.33	0.7	0.1	1.91	0.61	0.22
		Mean step time (<i>s</i>)	0.56 ± 0.08	0.55 ± 0.06	0.56 ± 0.8	2.26	0.84	0.06	1.3	0.61	0.20
		Mean stride time (<i>s</i>)	1.08 ± 0.12	1.1 ± 0.08	1.11 ± 0.92	1.37	0.5	0.2	0.001	0.88	0.26
		Mean swing time (<i>s</i>)	0.39 ± 0.06	0.40 ± 0.04	0.39 ± 0.54	1.06	0.49	0.2	0.67	0.24	0.24
		Mean step length (<i>meters, m</i>)	0.65 ± 0.07	0.61 ± 0.91	0.67 ± 0.55	2.74	0.09	0.53	2.28	0.11	0.72
		Mean step velocity (<i>ms⁻¹</i>)	1.18 ± 0.14	1.06 ± 0.27	1.19 ± 0.89	7.41	0.04*	0.62	4.67	0.17	0.26
Wearable Free-living Gait		Mean stance time (<i>seconds, s</i>)	0.66 ± 0.32	0.66 ± 0.25	0.66 ± 0.03	1.82	0.58	0.17	0.07	0.88	0.07
		Mean step time (<i>s</i>)	0.52 ± 0.21	0.52 ± 0.21	0.52 ± 0.02	0.17	0.43	0.26	0.18	0.44	0.16
		Mean stride time (<i>s</i>)	1.05 ± 0.44	1.04 ± 0.42	1.04 ± 0.05	0.24	0.5	0.22	0.11	0.71	0.2
		Mean swing time (<i>s</i>)	0.38 ± 0.14	0.38 ± 0.20	0.38 ± 0.02	1.04	0.43	0.25	1.65	0.88	0.37
		Mean step length (<i>meters, m</i>)	0.62 ± 0.43	0.62 ± 0.43	0.64 ± 0.02	3.35	0.32	0.31	4.29	0.69	0.61
		Mean step velocity (<i>ms⁻¹</i>)	1.18 ± 0.12	1.18 ± 0.12	1.24 ± 0.05	8.13	0.04*	0.64	6.51	0.04*	0.91

ⁱA lower score is better

ⁱⁱA higher score is better

8.4.5 Acute and post-season free-living gait follow up

Only step velocity within free-living assessment was significantly different ($p < 0.05$) across both pairwise comparisons (*nSRC* vs *pSRC* and *pSRC* vs *aSRC*) as detailed in Table 20. Free-living gait metrics were then interrogated for further analysis shown in table 5 to compare changes between a subset of participants to follow up post season ($n=5$). As shown in table 19 there were no significant differences between groups between the non-acute cohort in measures of free-living gait. Interestingly mean step velocity was significantly lower in the Acute SRC cohort during recovery (1.24 ± 0.05) and end of season (1.15 ± 0.04) with a large effect size of 1.6.

Table 20. Acute and post-season free-living gait follow up

Assessment Domain	Variable	No SRC History (<i>nSRC</i>)		Pairwise comparison (<i>nSRC</i>)			Acute SRC (<i>aSRC</i>)		Pairwise comparison (<i>aSRC</i>)		
		Baseline N=20 Mean \pm S.D	End season N=5 Mean \pm S.D	F	sig	d	During Season N=8 Mean \pm S.D	End of Season N=5 Mean \pm S.D	F	sig	d
		Wearable Free-living Gait	Mean stance time (<i>seconds, s</i>)	0.67 \pm 0.33	0.64 \pm 0.38	0.07	0.19	0.83	0.66 \pm 0.03	0.66 \pm 0.04	0.87
Mean step time (<i>s</i>)	0.52 \pm 0.24		0.51 \pm 0.02	0.33	0.21	0.66	0.52 \pm 0.02	0.52 \pm 0.03	0.28	0.98	0.02
Mean stride time (<i>s</i>)	1.05 \pm 0.43		1.01 \pm 0.06	0.43	0.14	0.77	1.04 \pm 0.05	1.04 \pm 0.07	0.53	0.89	0.08
Mean swing time (<i>s</i>)	0.38 \pm 0.14		0.37 \pm 0.03	1.92	0.30	0.54	0.38 \pm 0.02	0.38 \pm 0.02	0.26	0.89	0.08
Mean step length (<i>meters, m</i>)	0.60 \pm 0.67		0.58 \pm 0.42	0.68	0.58	0.28	0.64 \pm 0.02	0.64 \pm 0.02	0.11	0.81	0.14
Mean step velocity (<i>ms⁻¹</i>)	1.08 \pm 0.21		1.1 \pm 0.1	1.91	0.75	0.16	1.24 \pm 0.05	1.15 \pm 0.04	0.58	0.02*	1.6

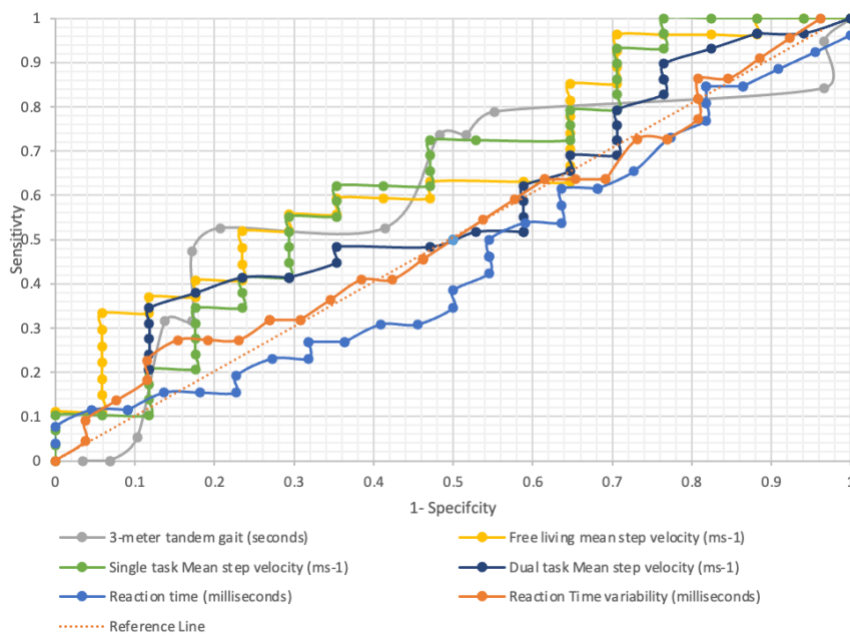
8.4.6 Sensitivity and specificity of significantly different metrics

Only characteristics with that were significantly different between groups were entered into the binary classification model for AUC and ROC. Results from the ROC analysis found that the 3-meter tandem gait walk time followed by mean step velocity (Free living, single task and dual task) was best at differentiating those with *pSRC* from *nSRC* history, as detailed in table 21 and figure 13A. Between those with *nSRC* and *aSRC* the mean step velocity in free living was best followed by symptom severity as shown in table 21 and figure 13B.

Table 21: AUC analysis across pairwise comparisons

Variable	<i>npSRC vs pSRC</i>	<i>npSRC vs aSRC</i>
	<i>AUC</i>	<i>AUC</i>
3-meter tandem gait (seconds)	0.69	-
Free living Mean step velocity (ms^{-1})	0.65	0.72
Single task Mean step velocity (ms^{-1})	0.63	-
Dual task Mean step velocity (ms^{-1})	0.61	-
Reaction time (milliseconds)	0.60	-
Reaction time variability	0.60	-
Symptom Severity (out of 132)	-	0.65

13A: SRC history vs no SRC history



13B: No SRC history vs acute SRC

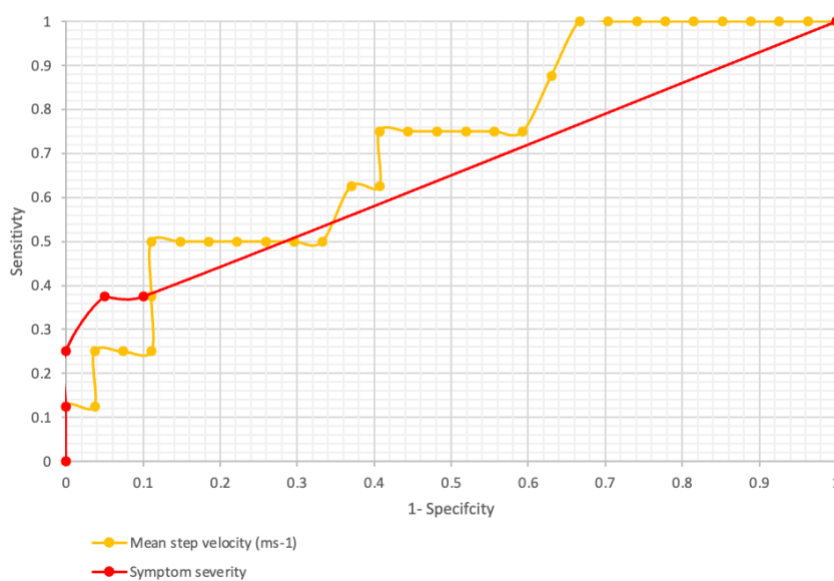


Figure 13. 13A ROC of those with SRC and those without SRC, 13B comparison between no SRC and acute SRC.

8.5 Discussion

Chapter 7 proposed a comprehensive multimodal protocol in mTBI/SRC assessment with the novel inclusion of free-living gait. There was opportunity and strong rationale for implementing and testing the use of digital approaches in their capacity as objective tools for assessment/monitoring. This chapter implemented portions of that protocol and also explored the practicalities and feasibility of conducting large scale multimodal assessment.

My exploratory results showed that free-living gait (i.e., step velocity) showed significant differences between all groups (pSRC, npSRC and aSRC), which may suggest potentially diagnostic use in revealing motor deficits between stages of mTBI. Other measures (SCAT symptom severity, reaction time) seem to have some capability to distinguish mTBI deficits between stages but not all i.e., are inconsistent in their diagnostic capabilities.

8.5.1 *Wearer adherence*

Overall, the wearable devices were moderately tolerated between groups and did not significantly differ. However, there were trends from the data suggesting those with acute SRC tolerated the devices more, and that it didn't impact their daily tasks. Furthermore, some players reported that during baseline testing they found the devices cumbersome to wear when at training or attending social events whereas those recovering from SRC were more restricted in the range of exercise/ active daily activities they would be participating in. Therefore, significant practical limitations were presented if data capture is required for over seven days as the players were reluctant in wearing, particularly in healthy baseline monitoring where they would be expected to have more of an active routine, whereas in recovery from acute SRC they are given guidance on activity modification and refrain from certain activities/behaviours (e.g., exercise, driving, and drinking alcohol).

8.5.2 *SCAT5: Limited capabilities*

Our results show that the SCAT5 did not show any significant differences between pSRC and nSRC (Table 17). This corroborates with previous literature outlined in chapters 2 of the potential subjectivity and low sensitivity associated with the SCAT5 when assessing players outside of acute timelines and even greater than seven days [66,67,81]. Other research has even suggested the effectiveness of the SCAT5 assessment decreases as soon as three days after injury [223]. Therefore, the reasons for no significant differences here may be related to the considerable chronicity in the previous SRC history (365 days). Additionally, some studies report that players can manipulate self-reported symptom scores during baseline assessment, allowing them to mitigate any poorer performance of scores when injured during the season [83]. Overall, this reinforces the challenges of relying on self-reported data may be particularly challenging in competitive environments where there is societal or financial gain in staying injury free.

In contrast, when examining those with aSRC and those with nSRC, there were significant differences found ($p=0.01$) in symptom severity. This finding is unsurprising given the very acute cohort, mean days post injury (5.75 ± 2.95) and is consistent with clinical guidelines on the use of SCAT5 in acute phases.

8.5.3 *Free-living gait: A useful diagnostic*

Analysis of over twenty different proxy measures of brain health found that free-living gait assessment was the most sensitive metric to distinguish acute SRC ($n=8$) and no previous SRC ($n=20$). The second most sensitive characteristic was symptom severity as part of the SCAT5 which is consistent with the body of literature when examining the acute (less than 7 days) and as discussed above [66,224].

As shown in figure 1B (ROC) analyses found that step velocity had the highest (AUC) of was the most accurate method of analysis and distinguishing non SRC (B) from SRC (A, C). But as this has yet to be tested in this cohort of university rugby athletes, we don't have a reliable comparison, but suggests further examination is warranted for more clarity on a clinically meaningful change.

My results do however corroborate with previous research in TBI and from laboratory-based assessment of individuals with SRC whereby the motor cortex involved with gait speed is impaired [225]. Examination of other cohorts (Parkinson's) also found differences with pathological cohort showing slower, shorter steps [90]. However, our result was also somewhat surprising with those with acute SRC walking faster than non-injured equivalents. This may be related to impaired motor control and or behavioural interaction. This increase in gait speed then levelling off has been seen and is consistent with other literature examining longitudinal assessment of gait after SRC in collegiate athletes suggesting gait deficits may take longer than other deficits to recover and return to baseline [226].

8.5.4 *Strengths and limitations*

Digital technologies such as IMU's have many advantages over traditional methods of assessment including objectivity and continuous data collection. In this study I alone (as a single clinician) was able to capture twenty measures of brain health using technologies and assess fifty players during baseline and during a season. This was feasible but challenging at times due to the recording and set up time associated with equipment and data download post session. Despite the wealth of data captured, it is unlikely that all physios or clinical staff will have the resources or time to complete a full multimodal assessment in their individual clinical setting. Therefore, the result from this study provides an initial signal and stratification for which variables (e.g., gait) and deficits to focus on in future research.

The primary strength of this study was the use of a single IMU to objectively measure free-living gait quality in a young health athletic population; the use of a single device and assessment within usual daily life means that subjects had longitudinal data collection carried after a battery of multimodal assessment [150]. I also quantified useful gait quality metrics which in future could be explored using (clinical-based) conceptual models [95,150,162]. Although use of a single IMU alone on the lower back facilitated more longitudinal data collection, significant challenges were encountered with wearer adherence and data loss associated. More emphasis should be given to why there was reduced adherence among players and improved patient/public involvement for future research. Future research should investigate participants longitudinally in including immediately post SRC and post season, as well as those who may have chronic symptoms or more severe TBI.

8.6 **Conclusion**

The concern about missed or delayed SRC diagnosis is growing, but methods to objectively monitor baseline performance and return to play after concussion are still lacking. This exploratory study showcased that multimodal baseline assessment was feasible in a low-resource setting and able to distinguish those who have a history of SRC and those without. Wearable technologies can yield additional data that traditional self-report approaches cannot, such as subtle physiological responses. Combining data from nondigital (traditional) and digital (wearable) methods may augment SRC assessment for improved objectivity in baseline assessment and subsequent RTP decisions.

In this chapter/study, I found that inertial wearables yielded useful objective data relevant to cognitive, gait and metrics in those with SRC history compared to the traditional assessment method (SCAT5). I found free living step velocity to be the best at distinguishing acute SRC from non SRC cohorts, in baseline assessment 3m tandem walk speed was the best in distinguishing those with no SRC history and those with a recent SRC (<12 months). This finding, that gait speed is of interest and may be a useful surrogate marker of recovery of those with acute SRC and those who may have deficits long after RTP and relates strongly to PoI3 for the objectivity of assessment.

Following exploration in young populations SRC history and no SRC history, the next chapter explores chronic mTBI. This is an important consideration given the large numbers of reported. Due to COVID, local recruitment was not possible (see chapter 7). Accordingly, although the next chapter uses data from a non-sporting context it continues to explore free-living gait as a diagnostic (bio) marker in those still reporting mobility deficits from impacts of mTBI, long after initial injury.

Chapter 9: Chronic mTBI: Exploring free-living gait as a diagnostic (bio) marker

This chapter uses text from my previously published online article to fit the context and narrative of this thesis. The journal article, *Free-living gait does not differentiate chronic mTBI patients compared to healthy controls* was published in the **Journal of NeuroEngineering and Rehabilitation** in 2022 (URL: <https://doi.org/10.1186/s12984-022-01030-6>)

9.1 Introduction

In my previous chapter I explored the use of multimodal baseline assessment and in particular gait as a possible SRC based diagnostic (bio) marker in a range acute mTBI. Accordingly, in this chapter I further explore free-living gait as a diagnostic but in a large cohort of chronic mTBI participants compared to healthy controls [99]. No study to date has comprehensively quantified free-living gait quality in chronic mTBI patients and healthy controls. Therefore, this research fills a gap which remains as to whether measures of free-living gait quality are impaired in chronic mTBI patients. As the increasing awareness of sub concussive impacts associated with SRC becomes apparent, there is demand for more passive longitudinal monitoring techniques. Greater understanding of how mobility is affected in free-living environments may uncover useful markers for subtle deficits in chronic mTBI patients and target areas for further research and or areas for (personalised) rehabilitation (PoI3).

9.2 Background

Motor, psychological and sensory deficits can be subtle and difficult to detect in mTBI and may persist for long periods after the initial injury (e.g., >3 months). Chronic symptoms post-mTBI can significantly impact quality of life and daily function, which can lead to prolonged issues/symptoms [227]. Physical/motor impairments are particularly prevalent in mTBI, with eight out of ten people with acute mTBI reporting balance impairments within a few days of the injury and three out of ten reporting longer-term (chronic) motor impairments [228–230]. Therefore, motor testing (e.g., gait) remains a crucial component of clinical assessment to quantify impairment across various mTBI timelines [20,69–71]. Understanding gait deficits may provide targets for rehabilitation as well as continued monitoring.

As highlighted in my previous chapter, monitoring mobility within free-living environments may provide a novel opportunity to detect subtle and meaningful deficits following mTBI. Elsewhere, results from laboratory-based objective gait assessment have also found pace-related gait deficits (stride length and gait speed) in chronic mTBI patients compared with healthy controls [183], suggesting gait may be a useful diagnostic marker of mTBI. While laboratory studies provide a foundation for evaluating the differences between healthy and impaired gait, laboratory-centric assessment methods are prescriptive in nature, and may mask subtle mTBI-related deficits that may otherwise occur within habitual (free-living) environments. Monitoring mobility/gait within free-living environments may therefore provide an opportunity to detect subtle and meaningful deficits following mTBI.

As described, IMUs can estimate mobility/gait and a variety of other outcomes[73,81,85,94–96]. Recent work has examined free-living IMU-based turning quality measures in chronic mTBI patients and controls, showing turning to be more sensitive in differentiating groups [86]. Specifically, those with chronic mTBI had larger, slower and more variable turns during daily life, but had a similar number of steps per day compared with controls [86]. While the previous study evaluated turning, it did not measure other gait quality metrics such as stride velocity, step length, or swing time. Additionally, while previous studies have examined mTBI gait in research settings, no study to date has comprehensively quantified free-living gait quality in chronic mTBI patients and healthy controls. Therefore, a gap remains as to whether measures of free-living gait quality outside of measures of turning are impaired in chronic mTBI. A greater understanding of how mobility/gait is affected in free-living environments may uncover useful markers for subtle deficits in chronic mTBI patients, providing insights if it can be a tangible diagnostic in this cohort. Accordingly, the study aims of this chapter were therefore to;

1. explore if free-living gait is impaired in people with chronic mTBI compared with healthy controls, and
2. determine the most sensitive free-living gait quality metrics that differentiate chronic mTBI patients from controls.

9.3 Methods

9.3.1 Participants

Thirty-two symptomatic chronic mTBI patients and 23 healthy controls participated. Participants were recruited as part of a larger study [221], through posters in athletic facilities, physical therapy clinics, hospitals, concussion clinics, community notice boards, and cafes in and around the Portland, OR metropolitan area. Patient demographics are shown in Table 1. Ethical approval was granted by the Oregon Health and Science University (OHSU) and Veterans Affairs Portland Health Care System (VAPORHCS) joint institutional review board with participants providing written informed consent before commencing the study.

9.3.2 Inclusion and exclusion criteria

Participants were included in the chronic mTBI group if they had had a diagnosis of mTBI based upon Veteran Health Administration (VHA) /Department of Defense (DoD) [233] criteria and who were greater than three months post mTBI with self-reported balance impairments. The control group consisted of those who had no history of brain injury in the last year. Additionally, mTBI patients were required to have minimal to no cognitive deficits as determined by the Short-Blessed Test (score ≤ 8) [234] and no peripheral vestibular or oculomotor pathology preceding their mTBI. Participants were excluded if they had any musculoskeletal injury which could impair their gait or balance or a recent history of moderate or severe substance abuse.

9.3.3 Gait analysis

Participants were asked to wear an IMU for 7 days, and participants with less than 3 days were excluded from analysis, in line with previous studies [86,213,214]. Participants wore a compact (L×W×H: 43.7×39.7×13.7 mm, 128 Hz) and lightweight (<25 grams) IMU (previously validated [235–237]) attached to a belt (128 Hz, Opal V1, APDM Inc., Portland, OR) that contained an accelerometer ($\pm 16g$, $\pm 200g$) and gyroscope (± 2000 deg/s). Participants wore the IMU around their waist for a minimum of 5 hours per day for up to 7 days using the protocol described previously [221] and [86]. Data were stored on the IMU internal storage (8Gb) and then downloaded via proprietary software (MobilityLab, APDM Inc., Portland, OR) to a laptop. The devices were charged everynight. Free-living data were then processed using custom-made and validated MATLAB® (MathWorks Inc, Massachusetts, USA) algorithms to estimate 12 free-living gait quality metrics [132,153,213,214]. As described in chapter 6, algorithms used in this thesis are device agnostic and can be equally applied to different IMU technologies.

Gait: Free-living measures of gait quality were calculated using a bespoke MATLAB® algorithm as follows. The waist worn IMU was used to examine orientation and periods of static and dynamic activity [132,153]. Subsequently, the latter were examined for initial and final foot contact events within the gait cycle via the continuous wavelet transform [145], where a bout/period of walking was predefined by a time period of between 0.25 and 2.25 seconds and ≥ 3 steps [118]. For the purposes of this study and examining a chronic cohort with self-reported mobility deficits, a movement bout was classified as >10 seconds. That was to ensure subtle deficits were captured. Gait quality metrics included mean; stance time (seconds, s), step time(s), stride time (s), swing time (s), stride length (centimetres, cm), stride velocity (centimetres per second, cms^{-1}).

9.3.4 Self-Reported symptoms

Chronic mTBI patients completed the NSI which is widely used in the assessment of mTBI symptoms [183,238]. The NSI is composed of 22 items within the questionnaire and recorded on a five-point Likert scale, with higher scores indicating more severe symptoms. The maximum a participant can score is 88. The NSI and subscales [239] have acceptable reliability in characterising presence and tracking severity of symptoms in TBI [239,240]. The NSI remains the cornerstone of clinical symptom

assessment and was determined as the appropriate method to capture self-reported impairments in the chronic mTBI patients.

9.3.5 Statistical analysis

Data were analysed in SPSS (v23, IBM) and R studio (Boston, MA, USA). All data were normally distributed as assessed with Shapiro-Wilks tests and therefore parametric tests were used. Independent t-tests were performed comparing demographic information between mTBI and control groups. To compare free-living gait quality metrics between chronic mTBI patients and controls, we used separate multivariate analysis of covariance (MANCOVA). MANCOVA was used to control for sex and age [98,241].

To estimate which gait quality metrics differentiated chronic mTBI patients from controls, we used ROC) and AUC analysis. ROC analysis provides a trade-off between specificity and sensitivity between the various free-living gait quality metrics and binary classification of either mTBI patients and healthy control. Statistical significance was determined at $p < 0.05$ (*two-tailed*) unless otherwise stated. Bonferroni corrected significance values were applied for multiple comparisons in free-living gait quality measures ($p < 0.002$). Effect sizes were described as interpreted as weak (< 0.50), moderate ($0.50 - 0.79$) or strong (> 0.80) as previously described [47].

9.4 Results

9.4.1 Demographics and clinical assessments

Demographic characteristics are presented in Table 22 for age (years), height (cm), mass (kg) and the number of days since injury and NSI for the mTBI group only. In our mTBI cohort, NSI total score was moderately high (5th to 9th percentile) compared to previously published normative mTBI scores, demonstrating that our chronic mTBI group was still symptomatic at least more than 3 months after injury [44]. SCAT results were substantially higher than the cohort examined in chapter 7.

9.4.2 Adherence to IMU sensor

Participants were asked to wear the IMU sensor for 7 days, but compliance was variable across both groups with several mTBI (n=16) and control (n=13) participants wearing the sensor for less than 7 days. Specifically, the mean number of days that the IMU was worn was 6.8 (± 2.4) days in the mTBI group and 6.04 (± 2.0) days in the control group which is higher than the cohorts explored in chapter 8. (npSRC 3.85 \pm 1.98 days, pSRC 4.55 \pm 1.98 days, aSRC 4.25 \pm 2.19 days).

9.4.3 Group differences in free-living gait

When controlling for age and sex, there were no significant differences in measures of free-living gait quality between chronic mTBI patients ($p > 0.05$) and controls. Descriptive data for free-living gait quality metrics are provided in Table 23.

TABLE 23. Participant demographics

	Controls (n= 23)	mTBI (n =32)	<i>p</i>
Age (years)	48.56 (22.56)	40.88 (11.78)	0.11
Sex (Male or Female) ^b	M(6) F(17)	M(6) F(26)	0.52
Height (cm)	165.46 (8.03)	168.51 (9.19)	0.22
Mass (kg)	68.03 (15.32)	76.17 (18.80)	0.25
NSI Total Score	-	35.88 (13.9)	-
NSI Vestibular	-	5.44 (2.22)	-
NSI Somatosensory	-	10 (4.92)	-
NSI Cognitive Score	-	8.34 (3.89)	-
NSI Affective Score	-	10.34 (5.64)	-
SCAT5 (Severity Total)	-	33.69 (19.44)	-
Days Since Injury ^a	-	440.68 (700.63)	-

^a Median and interquartile range. ^b chi-squared, Mean and standard deviation reported unless otherwise stated.

TABLE 22. Free-living gait quality metrics; group differences whilst controlling for age and sex, Area under the Curve (AUC)

Free-living gait metric	mTBI (n=32) Mean (S.D.)	Controls (n=23) Mean (S.D.)	F	p	d	AUC
Mean stance time (seconds, s)	0.83 (0.05)	0.85 (0.09)	0.19	0.66	0.00	0.44
Mean step time (s)	0.70 (0.05)	0.73 (0.09)	0.21	0.65	0.00	0.44
Mean stride time (s)	1.41 (0.10)	1.45 (0.18)	0.21	0.65	0.00	0.44
Mean swing time (s)	0.58 (0.05)	0.60 (0.09)	0.22	0.64	0.00	0.44
Mean stride length (centimetres,cm)	74.01 (4.10) (0.74, 0.04)	72.68 (3.60) (0.72, 0.04)	2.84	0.10	0.05	0.63
Mean stride velocity (cms ⁻¹)	105.59 (8.88) (1.05, 0.09)	101.34 (11.47) (1.01, 0.11)	1.37	0.25	0.03	0.60
Stance time variability CV (s)	0.20 (0.01)	0.21 (0.02)	0.03	0.87	0.00	0.49
Step time variability CV (s)	0.20 (0.01)	0.20 (0.02)	0.10	0.75	0.00	0.48
Stride time variability CV (s)	0.22 (0.01)	0.22 (0.01)	0.35	0.56	0.01	0.51
Swing time variability CV (s)	0.20 (0.01)	0.21 (0.02)	0.13	0.72	0.00	0.47
Step length variability CV (s)	18.62 (1.18)	18.32 (0.96)	2.30	0.14	0.04	0.61
Step velocity variability CV (cms ⁻¹)	36.90 (3.11)	35.48 (4.08)	1.18	0.28	0.02	0.60

Bolded p values: p < 0.05 (Bonferroni corrected p value 0.002). Group analysis of covariance results controlling for age and sex. mTBI, mild traumatic brain injury; S.D., standard deviation; CV, coefficient of variation, Cohens D effect size

AUC > 0.50 in italics and bold.

9.5 Discussion

This study progresses our previous work [3], which examined free-living activity quantity and turning quality measured by a single IMU in those with chronic mTBI compared to healthy controls. Free-living mobility assessment in chronic mTBI is still an emerging research area, but results from other neurological conditions (e.g., Parkinson's disease) suggest that impaired gait occurs in parallel with neurological dysfunction [48]. However, results in this study indicated that free-living gait quality was not significantly different between our samples of chronic mTBI patients and healthy controls (when controlling for age and gender). The absence of significant differences in this study are likely multifactorial and could involve both inherent limitations of self-reporting of issues, and the chronicity of this mTBI cohort. However, assessment of free-living mobility in chronic mTBI may still allow for improved diagnostics and monitoring of recovery within real-world environments, which is unachievable using analogue (non-digital) approaches or laboratory-based assessments only, but further research with longitudinal assessments following the initial injury would be required.

9.5.1 *Free-living gait*

Our results show that free-living gait quality metrics were not different between chronic mTBI and control groups, - which is surprising given this cohort had self-reported balance deficits. Overall research into chronic mTBI has yet to gain consensus on what specific measures can differentiate healthy people from those with mTBI [24]. Indeed, some laboratory-based studies have found pace-related deficits (stride length and gait speed) while other studies have found no differences outside of the acute timeframe (>10 days) [2]. Laboratory gait assessment does allow for more controlled assessment of complex tasks (e.g., dual-task, obstacle avoidance, etc.), which may be required to elicit or provoke gait deficits in chronic mTBI [2,49]. For example, dual-task laboratory assessment in people with chronic mTBI can reveal gait deficits in rhythm (stride time) [24]. However, complex laboratory tasks fail to fully replicate free-living environments where motor, cognitive and sensory function are continuously challenged [50]. Given these challenges in free-living environments, we were surprised that our measures of gait quality did not suggest impaired mobility in this chronic mTBI cohort.

The lack of significant differences and low effect sizes in gait quality measures between chronic mTBI patients and healthy controls may be related to the considerable chronicity (median 1.2 years post-injury) of this mTBI cohort. This duration may have resulted in the cohort developing chronic compensatory strategies over time to replicate 'normal' gait patterns during walking in their daily life. To fully understand this, future research should test participants in free-living environments longitudinally from the time of initial injury to better understand how gait changes acutely after mTBI and into more chronic stages. Similarly, although outside the scope of this thesis, incorporating assessment of turning during gait, which is a more complex task that is difficult to compensate for, may also reveal subtle mobility deficits [24,28,51]. Overall, there is no definitive way of objectively understanding the reasons for lack of differences in free-living gait quality between our cohorts of chronic mTBI patients and healthy controls. There are many unknown factors and contexts that affect free-living assessments. For example, here the environments participants were regularly walking in, the surfaces they walked on, or the types of terrain encountered were all unknown and such heterogeneity could impact results [52]. Equally, it is not possible to quantify the usual free-living mobility habits of the participants or to determine if this chronic mTBI cohort displayed any compensatory behaviour strategies (e.g., refraining from talking or performing other tasks whilst walking) that could further impact results. The introduction of egocentric video recordings of free-living mobility may enable greater insight and a robust reference to better understand the context of environments [53]. If used in conjunction with objective free-living IMU assessment, video data could yield even greater contextual understanding of free-living gait performance and any compensatory behaviour mTBI patients display within an environment.

9.5.2 *Strengths and limitations*

Digital technologies such as IMU's have many advantages over traditional methods of assessment including objectivity and continuous data collection. The primary strength of this study was the use of a single IMU to objectively measure free-living gait quality in chronic mTBI patients and controls; the use of a single device and assessment within usual daily life means that subjects had low research burden [54]. We also quantified useful gait quality metrics from clinical-based conceptual models from neurological-based research. Although use of a single IMU alone on the lower back facilitated more rapid data collection and reduced burden, it fails to quantify other useful gait characteristics which may provide more insight to dynamic postural control and environmental information i.e., step width and step width variability arising from uneven terrain [55]. Thus, future research should investigate additional gait characteristics (based on conceptual gait models) or a video-based wearable for a more informed free-living assessment. While I am not currently aware of any IMU-based technology to quantify step width during free-living, a computer vision-based approach has been suggested from a wearable camera [53]. Additionally, the outcome measures presented are primarily research-orientated, requiring a great deal of time-consuming post-processing and checking, which is based on prior experience of inertial data [56,57]. Therefore, there are needs to refine and deploy software that clinicians and patients can easily navigate, which would allow more widespread uptake and use by health professionals [57].

Future research should aim to use power calculations to ensure sufficient sample size and ability to detect small differences in results. Participants were assessed for ~7 days using a single IMU attached to a waist belt. However, variation in the exact length of time participants wore wearables (minimum three days) could introduce differences and therefore not reflect true habitual free-living mobility as used in other studies [48,58]. Using multiple IMUs may provide more detailed spatial and temporal data for turning, balance and gait as used in previous studies [24], but this carries different limitations, such as longer data download, processing complexity and increased wearer burden, limiting the practical or clinical application. This trade-off should be considered in future studies as a potential improvement to the assessment protocol. [59,60].

There were some additional limitations to this study. First, a more detailed demographic profile could be reported in future studies to derive further inferences about the free-living mobility results or underlying physiological mechanisms for persistent symptom and mobility deficits [24]. For example, the symptom questionnaires were limited to NSI and the SCAT that were only completed by the mTBI cohort, which limited any useful comparisons and inference on the relationship between groups [3]. Second, balance/mobility problems in the chronic mTBI group were self-reported with no baseline or robust analysis done to quantify the magnitude of impairment [3], with the many factors such as the previous history of mTBI and evidence of abnormal neuroimaging omitted [4,61]. Third, the differences in this mTBI cohort's chronicity are likely to limit the direct comparison with other studies. Our study's cohort was chronic with a median post-injury time greater than 1-year, which compared to other studies examining people post-mTBI is a longer time since injury [24,62].

9.6 Conclusions

My results demonstrate that free-living IMU-based gait quality metrics were not significantly different between patients with chronic mTBI and healthy aged-matched controls. Accordingly, gait as a diagnostic in chronic mTBI remains unfulfilled. However, I feel that this work provides a useful comparison to chapter 8 and lays the foundation for future work in this area. For example, future research should focus on (i) additional characteristics from conceptual gait models such as absolute (between left and right feet) asymmetry and variability during all bouts of gait and (ii) longitudinal analysis of chronic mTBI patients during different stages of recovery (acute to chronic) to holistically monitor mobility impairments and recovery. Improving objectivity in mTBI assessment will result in greater understanding of injury progression, recovery and rehabilitation across a variety of clinical settings including both sporting and nonsporting mTBI settings. Accordingly, the next chapter explores the effectiveness of rehabilitation in a comparative cohort of chronic mTBI (identified by my literature review as novel) and free-living gait as a response (bio) marker [99].

Chapter 10: Free-living gait as a response (bio) marker: Exploration within a pilot intervention

10.1 Introduction

This study progresses my previous work in the last chapter which examined free-living gait measured by a single IMU in those with chronic mTBI compared to healthy controls. Free-living mobility assessment in chronic mTBI is still an emerging research area, but results from other neurological conditions (e.g., Parkinson's disease) suggest that impaired gait occurs in parallel with neurological dysfunction [48]. Chapter 9 indicated that free-living gait quality was not significantly different between our samples of chronic mTBI patients and healthy controls (when controlling for age and gender) and so needs further investigation to determine diagnostic use. The absence of significant differences in this study are likely multifactorial and could involve both inherent limitations of self-reporting of balance issues, and the chronicity of this mTBI cohort. However, assessment of free-living gait in chronic mTBI may still allow for improved diagnostics and monitoring of recovery within real-world environments, which is unachievable using analogue (non-digital) approaches or laboratory-based assessments only. As such further research with longitudinal assessments following the initial injury would be required and if deficits are modifiable with rehabilitation. This is particularly relevant for those with chronic deficits resulting from recurrent exposure to sporting head injuries/SRC and associated risk of neurological disorders. Accordingly, this chapter explores instrumented gait as a response (bio) marker.

10.2 Background

Dynamic balance impairments are common following mTBI [246,247] and can result in significant difficulty returning to routine activities such as work [248]. The standard recovery time based on self-reported symptoms is typically within three months [249], but up to 64% of individuals may develop persistent and chronic (>3months) post-concussive symptoms [250]. Balance impairment can be a debilitating consequence of mTBI, affecting daily activities that involve standing and walking, as well as other complex motor tasks. Good performance in these tasks require adequate integration of visual, vestibular, and sensorimotor systems for maintaining balance.

Vestibular rehabilitation (VR) is often prescribed to treat people suffering from dizziness and imbalance, and is based on theories of habituation, adaptation, and sensory substitution [251]. Specifically, VR focusses on specific head and eye movements, head and trunk movements and varying balance conditions with evidence to suggest that VR can significantly improve self-reported and performance outcomes [228]. Furthermore, improvements have been seen even when initiation of VR occurs in more persistent stages after injury. For example, research has found a significantly higher proportion of individuals to be medically cleared to return to sport within 8 weeks of initiating cervical spine physiotherapy and VR treatment (73%) compared with control (7%) [252].

While the use of VR alone has provided promising results, augmented treatment techniques, such as the addition of biofeedback to VR has been posited to assist in the rehabilitative process of imbalance. Audio biofeedback (ABF) is one approach that may be beneficial for improving balance because it does not interfere with other sensory information important to balance control. ABF works by providing an auditory signal that corresponds with the direction of sway. For example, if a patient stands with their eyes closed and sways to the right, a tone in the patient's right ear will be heard telling the patient they are starting to go too far to the right. Research has suggested that the nervous system adapts to sensory information depending on the environment and on individual tendencies to rely on vestibular, somatosensory or visual information to control sway [253].

Although contemporary strategies exist, studies investigating best practice rehabilitation following mTBI have been limited, especially where persistent symptoms are involved [11,254,255]. This may not be unsurprising given the heterogeneity of response to mTBI [256,257] but there is one major challenge that still needs to be overcome, a lack of consensus pertaining to rehabilitation. Specifically, knowing what tools and arising outcomes/metrics are the most sensitive to change in those suffering from mTBI across different recovery timelines. A better understanding of those tools and outcomes could be used to better inform rehabilitation.

Currently, clinical assessment tools for assessing functional problems with balance and gait are limited. For example, the Balance Error Scoring System (BESS) remains the most frequently administered clinical balance assessment for those with suspected mTBI, and is recommended in the most recent consensus statement [20] in addition to a clinical pass-or-fail assessment of tandem gait. Both assessments provide low-resolution information and suffer from clinical subjectivity [176]. Furthermore, the BESS has been shown to have poor sensitivity [258] and lack quantitative ability to track recovery beyond acute stages of mTBI. Comparatively, instrumented assessments using wearable inertial sensors have shown greater promise in detecting long-lasting postural deficits [229,259–262] and gait impairment post-injury [263–266]. Of interest are the use of those technologies to gather free-living data, providing more insightful habitual gait data [86,256,267] and thus is the outcome of interest here.

Therefore, my colleagues and I at OHSU theorised that the additional sensory information from real-time ABF would complement VR in patients with chronic mobility deficits following mTBI by helping to shift sensory reliance from the visual system, known to be frequently impaired post mTBI [268]. By affecting that reliance, distorted central processing and sensory integration would be recalibrated, and in turn motor control would be improved. Should this type of rehabilitative intervention treat the cause effectively, then improved function and should occur within and beyond the laboratory setting where wearable inertial technology can capture objective data. Therefore; the aim of this chapter was to conduct a pilot study to determine if VR improved free-living gait and therefore its usefulness as a response (bio) marker.

10.3 Methods

10.3.1 Participants

Participants were recruited as part of a larger study [221], through posters in athletic facilities, physical therapy clinics, hospitals, concussion clinics, community notice boards, and cafes in and around the Portland, OR metropolitan area (similar to chapter 9). Ethical approval was granted by the Oregon Health and Science University (OHSU) and Veterans Affairs Portland Health Care System (VAPORHCS) joint institutional review board with participants providing written informed consent before commencing the study. Thirty-six symptomatic chronic mTBI patients participated, demographics are shown in Table 22. Of these thirty-six participants 24 were followed up post intervention.

10.3.1.1 Inclusion and exclusion Criteria

Participants were included in the chronic mTBI group if they had had a diagnosis of mTBI based upon Veteran Health Administration (VHA) / Department of Defense (DoD) [233] criteria and who were >3 months post mTBI with self-reported balance impairments. Additionally, mTBI patients were required to have minimal to no cognitive deficits as determined by the Short-Blessed Test (score ≤ 8) [234] and no peripheral vestibular or oculomotor pathology preceding their mTBI. Participants were excluded if they had any musculoskeletal injury which could impair their gait or balance or a recent history of moderate or severe substance abuse.

10.3.1.2 Intervention: VR+ABF

Full details of the VR+ABF intervention are described elsewhere [269]. In brief, participants received progressive (3 levels of difficulty) exercises that targeted gaze stabilization, vestibular stimulation, balance, and proprioceptive retraining. While performing the rehabilitation exercises participants also wore an ABF device, a lumbar-mounted smartphone (mHealth Technologies s.r.l., Bologna, Italy) which detects anteroposterior (AP), and mediolateral (ML) accelerations. Participants wore headphones and the ML inclination was encoded as a sound in either the left or right ear while the AP tilt was encoded as changes in pitch as the person leans backward or forward. When the body is in perfect equilibrium, the system is quiet. AP and ML feedback were supplied to the participant during static balance exercises. During dynamic balance exercises, ML feedback was provided only. During balance exercises, participants were instructed to utilize the auditory sounds provided by the ABF device to maintain balance and keep the system quiet. In discussion with OHSU colleagues a range of outcomes were quantified (e.g., turning) but free-living gait are presented here only to fit in the context of the thesis.

10.3.2 Assessment

10.3.2.1 Inertial-based wearable

Participants were asked to wear an inertial measurement unit (IMU which was the Opal V1, APDM Inc., Portland, OR) for 7 days as described in chapter 9.

10.3.2.2 Free-living gait

Free-living measures of gait quality were calculated using a bespoke MATLAB® algorithm as described in chapter 9.

10.3.3 Data collection

Demographic information (age, gender, height, weight, and date of injury), as well as symptom information (Dizziness Handicap Inventory [DHI] and Neurobehavioral Symptom Inventory [NSI]) were collected on each participant as part of the main study. Home monitoring data were collected over a period of one week immediately prior to, and immediately following a 6-week vestibular rehabilitation program. The IMU was worn for a minimum of 5 hours/day for up to 7 days using the protocol described previously [221][86]. Participants with less than 3 days of consecutive IMU wear were excluded from analysis, in line with previous studies [86,213,214].

10.3.4 Statistical analysis

Data were analysed in SPSS (v23, IBM) and R studio (Boston, MA, USA). All data were normally distributed as assessed with Shapiro-Wilks tests and therefore parametric tests were used. To compare free-living gait quality metrics between pre and post intervention we used separate multivariate analysis of covariance (MANCOVA). MANCOVA was used to control for sex, age, height and mass [98,241].

To estimate which gait quality metrics were most altered after vestibular rehabilitation mTBI patients from controls, we would use receiver operating characteristic (ROC) and area under the curve (AUC) analysis. ROC analysis provides a trade-off between specificity and sensitivity between the various free-living gait quality metrics and binary classification. However, as there were no statistically significant differences this was not included. Statistical significance was determined at $p < 0.05$ (two-tailed) unless otherwise stated. Bonferroni corrected significance values were applied for multiple comparisons in free-living gait quality measures ($p < 0.002$). Effect sizes were described as interpreted as weak (<0.50), moderate (0.50 -0.79) or strong (>0.80) as previously described [242].

10.4 Results

Demographic characteristics are presented in Table 24 for age (years), height (cm), mass (kg) and the number of days since injury and NSI for the mTBI group only. Many of the same cohort were also examined in a separate study detailed in chapter 9. In our mTBI cohort, NSI total score was moderately high (5th to 9th percentile) compared to previously published normative mTBI scores, demonstrating that our chronic mTBI group was still symptomatic at least more than 3 months after injury [44]. SCAT results were substantially higher than the cohort examined in chapter 7.

Table 24. Participant demographics

	<i>Pre-Intervention</i> (<i>n= 36</i>)	<i>Post Intervention</i> (<i>n =23</i>)
Age (<i>years</i>)	40.77 (11.58)	40.88 (11.78)
Sex (Male or Female) ^a	M(8) F(28)	M(6) F(16)
Height (<i>cm</i>)	169.55 (9.30)	169.74 (9.74)
Mass (<i>kg</i>)	77.40 (18.88)	77.90 (19.78)
Number of days post injury ^b	698.92 (744.29)	785.73 (848.06)
Sports Concussion Assessment Tool (SCAT5)	36.97 (21.97)	-
NSI Total Score	36.63 (13.78)	-
NSI Vestibular	5.31 (2.14)	-
NSI Somatosensory	10.17 (4.99)	-
NSI Cognitive Score	8.46 (3.89)	-
NSI Affective Score	10.86 (5.33)	-

^a Median and interquartile range. ^b chi-squared, Mean and standard deviation reported unless otherwise stated. mTBI, mild traumatic brain injury; NSI – neurobehavioral symptom inventory

10.4.1 Demographics and clinical assessments

Demographic characteristics are presented in Table 1 for age (years), height (cm), mass (kg) and the number of days since injury and NSI for the mTBI group only. In our mTBI cohort, NSI total score was moderately high (5th to 9th percentile) compared to previously published normative mTBI scores, demonstrating that our chronic mTBI group was still symptomatic at least more than 3 months after injury [239].

10.4.1.1 Adherence to rehabilitation

Participants were asked to wear the IMU device for 7 days pre- and post-intervention and in rehabilitation. Overall compliance to rehabilitation was high (90 ± 13.83 %).

10.4.1.2 Group differences in free-living gait

Multivariate analysis showed there was an interaction effect of the combined model (age, height, mass, gender and time) and individual differences based on age and mass (Subsequent analysis found that individually there were no significant differences pre- and post- rehabilitation in any gait characteristic. Descriptive data for free-living gait quality metrics are provided in Table 24. Overall, the lack of differences in free living measures may suggest gait is not modifiable in this rehab protocol or the effects were too small to detect.

Table 25. Multivariate model with covariates

Effect	Value	F	p	d
Combined	0.36	14.53	0.00*	0.65
Age	0.77	2.43	0.04*	0.23
Height	0.83	1.60	0.17	0.25
Mass	0.75	2.69	0.03*	0.25
Gender	0.92	0.70	0.66	0.08
Time (pre and post rehab)	0.92	0.622	0.68	0.08

Table 26. Free-living gait quality metrics; independent sample group differences

<i>Free-living gait metric</i>	<i>Pre(n=36) Mean (S.D.)</i>	<i>Post (n=23) Mean (S.D.)</i>	<i>F</i>	<i>p</i>	<i>d</i>
Mean stance time (<i>seconds, s</i>)	0.90 (0.07)	0.89 (0.06)	0.01	0.33	0.26
Mean step time (<i>s</i>)	0.78 (0.06)	0.76 (0.06)	0.03	0.34	0.26
Mean stride time (<i>s</i>)	1.56 (0.13)	1.53 (0.11)	0.01	0.34	0.26
Mean swing time (<i>s</i>)	0.65 (0.06)	0.64 (0.05)	0.01	0.36	0.25
Mean stride length (<i>meters,m</i>)	0.47 (0.07)	0.46 (0.09)	0.2	0.73	0.09
Mean stride velocity (<i>ems⁻¹</i>)	0.99 (0.15)	0.96 (0.19)	0.4	0.64	0.12
Stance time variability CV (<i>s</i>)	0.94 (0.03)	0.93 (0.03)	0.02	0.38	0.24
Step time variability CV (<i>s</i>)	0.87 (0.03)	0.87 (0.03)	0.02	0.39	0.23
Stride time variability CV (<i>s</i>)	1.23 (0.05)	1.22 (0.04)	0.01	0.39	0.23
Swing time variability CV (<i>s</i>)	0.80 (0.03)	0.79 (0.03)	0.01	0.42	0.22
Step length variability CV (<i>s</i>)	0.66 (0.05)	0.65 (0.08)	0.33	0.68	0.11
Step velocity variability CV (<i>cms⁻¹</i>)	0.96 (0.08)	0.94 (0.12)	0.58	0.63	0.13

Bolded p values; $p < 0.05$ (Bonferroni corrected p value 0.002).-Group analysis of covariance results controlling for age and sex. mTBI, mild traumatic brain injury; S.D., standard deviation; CV, coefficient of variation, d, Cohens d effect size F Wilks' λ ,

10.5 Discussion

The results demonstrate that free-living IMU-based gait quality metrics were not significantly different between patients with chronic mTBI pre and post rehabilitation. Overall, the lack of differences in free living measures may suggest gait is not modifiable in this rehab protocol or the effects were too small to detect. However, there were significant interaction effects for multivariate model where I controlled for a number of covariates, whereby age and weight were significantly different ($p>0.05$) but not time (pre- versus post- rehabilitation)

10.5.1 Free-living gait

Multivariate analysis showed there was an interaction effect of the combined model (age, height, mass, gender and time) and individual differences based on age and mass ($p>0.05$). Subsequent analysis found that individually there were no significant differences pre and post rehabilitation in any of the gait characteristics. Overall, the lack of differences in free living measures may suggest gait is not modifiable in this rehab protocol or the effects were too small to detect. Accordingly, its use as a response (bio) marker remain unfulfilled. However as outlined in chapter 9 this study's cohort was chronic with a median post-injury time greater than 1-year, which compared to other studies examining people post-mTBI is a longer time since injury [84,183]. This may mean the cohort developed other compensatory strategies that masked or did not change the resulting gait metrics.

Despite this lack of significant findings herein, I feel that there is value in undertaking free-living mobility assessments. This study has further highlighted that a single IMU can obtain a wealth of continuous free-living gait quality measures in people with symptomatic chronic mTBI and be used across a pilot rehabilitation programme. Thus, while this exploratory study indicated no between group differences, I feel that this work provides a useful comparison to chapter 7 and foundation for future work in this area, and unique comparison to the acute SRC cohort.

10.5.2 Limitations

Consistent with chapter 9, there are a number of limitations to this study. First, a more detailed demographic profile could be reported in future studies to derive further inferences about the free-living mobility results or underlying physiological mechanisms for persistent symptom and mobility deficits [24]. For example, the symptom questionnaires were limited to NSI and the SCAT that were only completed by the mTBI cohort pre intervention, which limited any useful comparisons and inference on the relationship between groups pre and post intervention [3]. Second, balance/mobility problems in the chronic mTBI group were self-reported with no baseline or robust analysis done to quantify the magnitude of impairment [3], with the many factors such as the previous history of mTBI and evidence of abnormal neuroimaging omitted [4,61]. Third, the differences in this mTBI cohort's chronicity are likely to limit the direct comparison with other studies. This study's cohort was chronic with a median post-injury time greater than 1-year, which compared to other studies examining people post-mTBI is a longer time since injury and may influence both the biological and social propensity to respond to intervention [24,62].

10.6 Conclusion

Our results in chapters 8 and 9 demonstrate that free-living IMU-based gait quality metrics were not significantly different between patients with chronic mTBI and healthy aged-matched controls. Despite a lack of significant findings here (and chapter 9), I feel that there is value in undertaking free-living mobility/gait assessments. These studies highlighted that a single IMU can obtain a wealth of continuous free-living gait quality measures in people with symptomatic chronic mTBI and healthy controls. Thus, while these exploratory studies indicated no definitive insights to diagnostic or responsive (bio) markers, I feel that this work provides a useful comparison to SRC cohorts and also foundation for future work in this area (e.g., additional characteristics from conceptual gait models and longitudinal analysis of SRC/mTBI patients during different stages of recovery, acute to chronic) to holistically monitor mobility impairments and recovery. That will continue the improvement and objectivity in mTBI assessment which will result in greater understanding of injury progression, recovery and rehabilitation across a variety of settings.

Chapter 11: Discussion, conclusions and wider impact

11.1 Introduction

This concluding chapter summarises my thesis. I recount key challenges of mTBI within the sporting context. I believe that my findings and the wider contribution to knowledge will be useful to better inform player health and welfare. I also highlight some extraneous limitations, wider research impact and recommendations for future research.

11.2 Addressing pragmatic challenges

As highlighted in chapter 1, there are many ongoing challenges to better inform mTBI management stemming from SRC. To grasp some of those challenges, rugby union helped frame a few for the context of this thesis and my professional ambition to improve patient care. Although there are well financed mechanisms at the elite rugby level, there is a dearth of categorically approved tools in general and next to none when providing routine care at amateur/community levels. Broadly, I defined 3 points of interest to define the early chapter of this thesis to inform possible tools to improve mTBI arising from SRC. Specifically, I considered PoI1 (finance/resources), PoI2 (access, scalability and consistency) and PoI3 (personalised assessment) to be necessary drivers of change to inform contemporary mTBI management. Achieving a digital approach encompassing those three would help fulfill an unmet (clinical) need.

11.2.1 *The role of digital technologies: Part 1*

Chapters 2 provided an examination of the literature, traditional and contemporary. There was a focus on harmonizing work within the field to shed light on research gaps and where the use of digital technologies may succeed. Some new affordable (PoI1) technological findings emerged namely, the opportunity for free-living (remote) multi sensing modalities, and use of digital gait outcomes as possible *diagnostic* and *response* (bio) markers. Technical requirements detailed in chapter 3 provided an investigation and understanding of an inertial wearable in a low-resource environment (chapter 4), detailing the technology as a valid and pragmatic tool to inform gait to screen and distinguish those with mTBI. Chapter 5 then went beyond a supervised setting to explore free-living habitual mTBI gait assessment as part of a single subject report. In those later chapters my findings supported the inertial gait approach to address PoI2 and PoI3 i.e., consistent objective data to provide personalised insights.

11.2.2 *The role of digital technologies: Part 2*

Lessons learned (chapters 1 to 6) enabled me to devise a thorough and comprehensive protocol to inform a contemporary mTBI assessment, chapter 7. The protocol is wide-ranging to generally inform the area of mTBI, but some of the suggested methods for analysis are purposefully excluded in later chapters to ensure clarity and focus within the context of this thesis. Due to COVID-19 I was not able to capture as many participants as planned (n=200). Additionally, there were many challenges that became apparent in following players up post injury, with many unable to complete the necessary visits post season due to e.g., study and exams. Regardless, I was able to gather a sufficient dataset to explore instrumented lab and more uniquely, free-living gait. Accordingly, chapter 8 showed the latter was (somewhat) practical and feasibility during a thorough multimodal assessment. More importantly, in chapter 8 I found evidence which suggested that free-living gait (step velocity) to be useful as a diagnostic (bio) marker i.e., to distinguish acute mTBI from controls. Of note, 3m tandem walk speed also seemed useful to distinguish those with a recent SRC (<12 months) to controls. This finding is of interest and may be a useful surrogate marker of recovery of those with acute SRC and those who may have deficits long after RTP.

In chapters 9 and 10 I explored instrumented gait in chronic mTBI, but from an independent dataset due to impact of COVID. Specifically, I examined the diagnostic (chapter 9) and response (chapter 10) of instrumented free-living gait. My results demonstrated that there were no significant differences between groups to categorically define diagnostic or responsive free-living gait markers. Despite those results, I feel that there is value in undertaking free-living mobility assessments. These chapters/studies

highlighted that a single IMU can obtain a wealth of continuous free-living gait characteristics in people with symptomatic chronic mTBI and controls. I also believe that this work also provides a useful comparison to SRC cohorts and a foundation for future work in this area. This will continue the improvement and objectivity in mTBI assessment which will result in greater understanding of injury progression, recovery and rehabilitation across a variety of clinical settings including both sporting and nonsporting mTBI settings.

11.3 Addressing my hypothesis

My central hypothesis was:

The use of digital technologies may enable affordable mTBI management, ensuring continuity (e.g., between assessors) while offering more objective personalised assessment to support traditional approaches

From my work undertaken in this thesis I believe my hypothesis to be valid. This thesis generally supports the suggested use of digital technologies as an affordable and objective method to support traditional approaches of assessment in mTBI/SRC. Moreover, the use of instrumented (lab) and free-living gait may fit that context with evidence of its use as a diagnostic tool. More work is needed to strengthen that claim as well as further investigate its use as a responsive tool.

11.4 Contribution to knowledge

My multidisciplinary approach reveals that focusing on one impairment in mTBI/SRC is unlikely to reveal meaningful insight to mTBI management and RTP (chapter 2). Instead, multimodal digital technologies could enable affordable management, ensuring continuity (e.g., between assessors) while offering objective but personalised data to better support traditional approaches (chapters 4-5). My results provide insight to the usefulness of instrumented free-living gait speed (step velocity) as a digital diagnostic (bio) marker for mTBI management (chapter 8).

One notable technical learning from the earlier chapter was the shift to using a more user-friendly equivalent technology, McRoberts Dynaport system from the AX6 which can be easier to deploy in uninjured active cohorts (chapters 5-7). In a purely computing science context, my findings have uncovered challenges and opportunities for further refinement. For example, there is still room for more 'no code' solutions in gait and algorithm analysis. Few clinicians would have the technical skillsets for completing free-living gait analysis. Therefore, validated algorithms within a "drag and drop", click and collect approach is needed to meet the recommended approach of remote, free-living monitoring of habitual behaviours. That is an important next step for the translation of academic research grade devices to be used more widely in clinical practice.

11.5 Limitations

COVID-19 has significantly affected my PhD topic as no contact sport has been played until restarting full in Summer/Autumn 2021. Although that brought about many challenges, including a reduced opportunity to collect longitudinal data sets, outlined in our protocol across additional cohorts (e.g. Womens Rugby), it afforded me an opportunity to adapt by creating new opportunities for data collection and collaboration whilst COVID restrictions have limited my primary data collection in the UK. This is exemplified with collaborations with Oregon Health State University to work collaboratively on equivalent and complementary datasets in mild traumatic brain injury (mTBI) presented in chapters 9 and 10. However as highlighted in chapter 9 and 10 the considerable chronicity within this cohort post injury may have limited the comparison to more acute cohorts. Equally there are many unknowns about the social and medical history of this cohort, such as pre-morbid physical status, psychosocial assessment which are known to influence recovery[270], which also limits the usefulness to compare to more comprehensive baseline in chapter 8. Future research should also include the investigation of additional gait characteristics (based on conceptual gait models model [97]) for a more

informed free-living assessment interpretation. Despite the nature of gait models being heterogenous with many different groups defining their own different conceptual models to classify and interpret a range of gait-based outcomes, there is opportunity to harmonise and develop an acute mTBI/SRC model of gait to allow closer comparison to other pathological cohorts (e.g elderly, parkinsons and stroke) [271]. It has also been recognised that the stratified employment (e.g. collecting data for, 1 vs 7 days) or duration worn by players or participants can be inconsistent across studies [271]. Equally the context by which free living gait data is collected in is heterogenous, in particular in younger active populations. Moving forward it is likely subsets of confirmatory video-validated free-living datasets would better support collaboration, harmonization across research groups [271].

11.6 Wider impact and future focus

I truly believe mTBI/SRC is at a crossroads in terms of both the way in which it is viewed by the general public, sporting bodies and players. The plight of recent players who unfortunately have been diagnosed with suspected early onset dementia or functional cognitive disorder further raises awareness of the risks of inappropriate management and overexposure of head trauma in sports[1]. This new and emerging evidence also shows the interconnected nature of mTBI and SRC with longer term neurological disorders [2]. As highlighted in chapter 1, Will Hooley suggested that mTBI/SRC previously viewed as non-harmful and short lived, but now lack of intervention concerning the longer terms impacts are now catching up unfortunately for both players and governing bodies. This has coincided with accusations of academic dishonesty among the concussion consensus statements lead author and expert committee has created a perfect storm of disruption [3]. Accordingly, in this period of disruption, in my opinion there is an opportunity to recalibrate the future of mTBI /SRC assessment, management and treatment. It also provides an opportunity to see mTBI/SRC assessment in the wider healthcare ecosystem and landscape. For example, important themes researched during my PhD but outside the scope of this thesis should be investigated in more detail under the move to multimodal approaches. Here are three topical examples learned from my wider PhD studies.

11.6.1 Open digital assessment tools

As highlighted and realised across many chapters, the challenges and reliance subjective approaches carries significant limitations for the assessment of players and ultimate health/welfare of players. As the field moves towards using more digital approaches such as wearables, there is a need to consider the wrap around and complementary approaches which underpin and will be widely used by clinicians such as the SCAT5. An open, digital equivalent may facilitate more efficient and transparent assessment, like the apps presented in chapter 2. During my PhD research I have been involved with co-creating an iOS SCAT5 app (appendix 6) to enable an Internet of Things (IoT) assessment, a first next step in this journey will be gaining user feedback and testing to ensure suitability for widescale deployment. The net benefit of moving towards digital symptom recording, which will allow greater understanding and co-investigation of the prognostic value of other SRC impairments.

11.6.2 Investigation motor impairments: Sleep

Recent research has indicated there may be subtypes of post-concussion presentation specifically linked to sleep disturbance [274]. Although a detailed evaluation of sleep metrics was outside the scope of this thesis, inertial wearables may be able to provide additional nocturnal data for inference of sleep quality and monitoring. For example, in Appendix 5 I provide a preliminary proof of concept for the use of a single wearable (AX6) to detail sleep quality in conjunction with remote gait assessment as it is an analysis of the same inertial data. Specifically raw IMU accelerometer data were used to broadly examine and compare nocturnal/sleep activity at different times. This was able to show notable differences between timepoints with greater frequency of movement as defined by the changing orientation of the accelerometer signal resulting in visual differences between sleep analysis timepoints with increased sleep disturbances immediately post-SRC compared to 1-month post-SRC and once RTP. This can be explored in further detail to examine with other mobile technologies such as

electroencephalogram (EEG) and or traditional approaches such as sleep diaries to augment SRC sleep deficit monitoring. Next steps should include exploring alternative wearable IMU-based algorithms for a more robust sleep analysis [5,6]. Future studies may consider the use of different/multiple wearable technologies for combinatory day and night/sleep assessments, although that approach would increase the complexity of data synchronization/processing and wearer adherence considered.

11.6.3 Improved understanding of contexts free-living data is collected in

Computing methods to inform environmental context to enhance remote/free-living inertial wearable gait outcomes remain underdeveloped. As identified in chapter 9, there are many unknown factors and contexts that affect free-living or remote assessments. An example being the environments participants were regularly walking in, the surfaces they walked on, or the types of terrain encountered were all unknown and such heterogeneity could impact results [7]. Equally, it is not possible to quantify the usual free-living mobility habits of the participants or to determine if acute SRC or chronic mTBI cohorts displayed any compensatory behaviour strategies (e.g., refraining from talking or performing other tasks whilst walking) that could further impact results.

Currently, remote/free-living inertial-based wearable gait analysis cannot absolutely/comprehensively determine if gait variations are due to intrinsic (physiological) or extrinsic (environmental) factors. However, for the purposes of this research and similar to other research, I assumed the unknown contexts (e.g., walking environment and types of terrain encountered) were heterogenous to impact results [244]. Equally, it is not possible to quantify if different free-living mobility habits or if people display any compensatory behaviour strategies (e.g., refraining from talking or performing other tasks whilst walking) which may further impact results. These suggestions may explain why there are differences between supervised and unsupervised wearable gait assessment and lack of differences in chronic cohorts (chapters 9 and 10). Future research should investigate the contexts of free-living assessment as previously described with wearable camera technology [190,191]. A logical next step would be introduction egocentric video recordings of free-living mobility may enable greater insight and a robust reference to better understand the context of environments [8]. If used in conjunction with objective free-living IMU assessment, video data could yield even greater contextual understanding of free-living gait performance and any compensatory behaviour mTBI patients display within an environment. This suggestion of combining multiple technologies and approaches is an important one and as such, below I highlight the wider issues of sustainability and moving wearables into everyday practices.

1.1.1 Making the leap into pragmatic use

The following examples are within the context of low-resource, observational or remote assessment and may provide some food for thought. As highlighted, there are opportunities within the topic of mild traumatic brain injury (mTBI) arising in sports but the prevalence of mTBI is much broader when considering e.g., older adult fallers or road traffic accidents equating to over 1.5 million accident and emergency admissions in the UK each year [30,31].

Clinicians working as first responders in the community or in sport often have the challenge of making rapid decisions on the severity of an injury - deciding on whether the patient needs to be sent to A&E for further assessment or equally if it is safe for them to return to play after recovery. Consider the scenario that a accelerometer-based wearables are widely deployed and pre-programmed with a validated algorithm and then activated for a person with suspected mTBI to assess their gait and balance, offering the clinician more objective and high-resolution data to better inform their clinical decision-making process. Alternatively, consider a scenario that the person may have repeated mTBI's (from playing e.g., rugby or American football or perhaps it is an older adult who is a repeated faller) [32,33]. Perhaps they already have the wearable at home from a previous meeting with the clinician or it is a wearable that was purchased for private use. These technologies may negate some of the challenges of solo working, whereby decisions for complex injuries or life-threatening injuries are made on the

information available at the time and clinical judgement. Overall, more widespread use of digital technologies and 5G-enabled telemedicine could enable real-time multidisciplinary decision-making involving doctors, first responders and sports professionals. By relaying vital signs and live images to trauma centres, alongside the data captured from wearables, second opinions can be used to help triage and prioritise those with the most urgent clinical need for hospital intervention, while enabling those with less severe clinical need to be monitored in alternative settings during their recovery. This may help reduce the risk of unnecessary A&E assessment while improving the reassurance provided to patients during their recovery [34].

11.7 Closing summary

As a qualified physiotherapist the associated challenges of diagnosing and identifying mTBI were very apparent during my clinical practice. It is now clear and apparent that the traditional tools and techniques used to diagnose and help my patients were lacking and adoption of new approaches which could enhance clinical assessment (e.g., digital approaches) restricted to distinct clinical environments. Wearables such as those described in my thesis, do provide affordable objective methods to support traditional approaches, but these findings should be carefully considered against the wider determinants of health, where sustainability is now of utmost importance. Definite and sustained changes will only be possible when viewing change through an ecosystem which will bring about the desired actions and outcomes much faster than without collective action.

Overall passive monitoring solutions such as wearables are becoming ubiquitous in daily life. Identifying useful digital biomarkers in pathological cohorts such as mTBI may improve the detection of injuries and better inform (personalised) safe RTP. Identifying stages of recovery more accurately reduces the likelihood of premature return to play or activity before full recovery and is a necessary threshold in offering personalised care and rehabilitation. Wearables could also directly provide more sustainable healthcare as well as indirectly offering personalised and decentralised approaches in medicine. Fundamental sensing requirements exist across a range of conditions (silent pandemic) but actioning novel approaches through prescribed software could provide the necessary steps in the overall journey in concurrent health and sustainability ambitions. My aim of this thesis was to contribute to the body of knowledge that seeks to improve the confidence and quality of care delivered for those with mTBI in SRC. I feel very grateful to have contributed and advanced the body of knowledge in this field and look forward to continuing to do so hereafter.

Appendices

Appendix 1. Full Publication list and outputs

1. **Powell D**, Stuart S, Godfrey A. “Sports Related Concussion: Digital Approaches for Targeted Player Management – A Narrative Review” : Lead author *Nature Partnership Journal: digital medicine* (December 2021) IF: 11:34)
2. **Powell D**, Godfrey A, Parrington L, Campbell K, King A, Stuart S, “Free Living turning not gait, better differentiates people with chronic mild traumatic brain injury from controls” *Journal of NeuroEngineering and Rehabilitation* (2022) IF:3.52
3. **Powell D**, Stuart S, Godfrey A. “Examining an open source inertial-based wearable for instrumented physical capability”.*Physical Therapy* (2022) IF:3.7
4. **Powell D**, Stuart S, Godfrey A. “The use of wearables in the assessment of SRC: A protocol for multimodal assessment”. *PLOS One* (2022) IF:3.7
5. **Powell D**, Nourandesh M, Tsung J, Stuart S, Godfrey A. “Investigating the AX6 inertial-based wearable for instrumented physical capability assessment of young adults in a low-resource setting” *Smart Health* (2021) IF:2.7
6. **Powell D**, Stuart S, Godfrey A. Investigating the Use of An Open Source Wearable as a Tool to Assess Sports Related Concussion: *Physiotherapy*, May 2021 IF: 2.45
7. **Powell D**, Stuart S, Godfrey A. “Objective measures of brain health: a pilot study with a somatosensory device in rugby union”: *Physiotherapy*, May 2020 IF: 2.45
8. **Powell D**, Stuart S, Godfrey A. “Wearables as objective tools in sport-related concussion: a protocol for more informed player management”: *Physiotherapy*, May 2020 IF: 2.45
9. Nourandesh M, Godfrey A, **Powell D**, Tung J. “Deep egocentric vision-based detection of older adults’ everyday walking surfaces for gait and fall risk assessment in the wild *Journal of NeuroEngineering and Rehabilitation* (2022) IF:3.52
10. Dever T, Powell D, Graham L, Mason R, Das J, Marshall S, Vitorio R, Godfrey A, Stuart S Gait Impairment in Traumatic Brain Injury: A Systematic Review *Sensors* (2021) IF:3.5
11. Celik, Y., **Powell, D.**, Woo, W. L., Stuart, S. & Godfrey, A., “A feasibility study towards instrumentation of the Sport Concussion Assessment Tool (iSCAT): *Annual international conference of the IEEE Engineering in Medicine and Biology Society*, July 2020
12. Coman B, **Powell D**, Das J, Graham L, Mason R, Harrison M, Rae G, Vitorio R, Godfrey A, Stuart S “Active rehabilitation following acute mild traumatic brain injury: A systematic review”, *Physiotherapy Canada* IF:0.65
13. Mason R, Byerley J, Baker A, **Powell D**, Pearson L, Barry G, Godfrey A, Mancini M, Stuart S, Morris R “Suitability of a low-cost wearable sensor to assess turning in healthy adults” *Sensors*, (2022) IF:3.58
14. Wall C, **Powell D**, Young A, Zyna A, Stuart S, Covassin T, Godfrey A “A deep learning-based approach to diagnose mild traumatic brain injury using audio classification” *PLOS One* (2022) IF:3.7

Book Chapters

1. Celik Y, Vitoria R, **Powell D**, Moore J, Young F, Coulby G, Tsung J, Stuart S, Godfrey A. Sensor Integration for Gait Analysis, *Encyclopedia of Sensors and Biosensors Elsevier*, 2022
2. **Powell, D.**, Celik, Y., Trojaniello, D., Young, F., Moore, J., Stuart, S. & Godfrey, A. "Instrumenting traditional approaches to physical assessment": Book chapter author, *Digital Health: Exploring the use and integration of Wearables, Elsevier*, May 2021
3. Stuart, S., **Powell, D.**, Marshall, S., Clark, C., Martini, D., Johnson, W. & Godfrey, A. "Sports Medicine: bespoke player management", Book chapter author, *Digital Health: Exploring the use and integration of Wearables, Elsevier*, May 2021

Conference Presentations

1. **Powell D**, Stuart S, Godfrey A. "Exploring digital Sports Related Concussion (SRC) assessment, performed by a single clinician", International Consensus Concussion Conference Amsterdam, October 2022
2. **Powell D**, Stuart S, Godfrey A. "Exploration of single and dual task gait and turning in Sports Related Concussion" International Society of Gait and Posture, Montreal July 2022
3. Barker L, Coulby G, Young F, Bowen S, Das J, Stuart S, Godfrey A, **Powell D** "OpenSCAT: Towards the development of an open and extensible sports concussion assessment tool to support IoT-based athlete monitoring systems" *43rd Annual Conference of IEEE Engineering in Medicine & Biology Society* November 2021
4. **Powell D**, Stuart S, Godfrey. Development Of An Open-Source Mobile Sports Concussion Assessment Tool *North East Post-Graduate Conference, UK November 2021*
5. **Powell D**, Stuart S, Godfrey A. Instrumentation in Sports Related Concussion: "Proposing inertial wearables and outcomes as objective tools", *25th Annual Congress of the European College of Sports Science, Seville*, November 2020
6. **Powell D**, Stuart S, Godfrey A. "Investigating the use of an open source wearable as a tool to assess Sports Related Concussion": *Chartered Society of Physiotherapy Conference, UK, November 2020*
7. **Powell D**, Stuart S, Godfrey A. "Instrumentation in Sports Related Concussion, proposing inertial wearables & outcomes as objective tools", *North East Post-Graduate Conference, UK November 2020*
8. Celik Y, **Powell D**, Stuart S, Godfrey A. "A feasibility study towards instrumentation of the Sport Concussion Assessment Tool (iSCAT): co-author *Annual international conference of the IEEE Engineering in Medicine and Biology Society*, July 2020
9. **Powell D**, Stuart S, Godfrey A. "Objective measures of brain health, a pilot study with a somatosensory device in rugby union" *Chartered Society of Physiotherapy Conference 2019, UK, Nov 2019*
10. **Powell D**, Stuart S, Godfrey A. "Wearables as objective tools in Sports Related Concussion assessment: a protocol for more informed player management *Chartered Society of Physiotherapy Conference 2019, UK November 2019*
11. **Powell D**, Stuart S, Godfrey A. "Wearables as objective tools in Sports Related Concussion assessment: a protocol for more informed player management", *North East Post-Graduate Conference, UK, November 2019*

12. **Powell D**, “Objective measures of brain health, in university rugby union” *Edinburgh Sports Medicine Conference, September 2019*

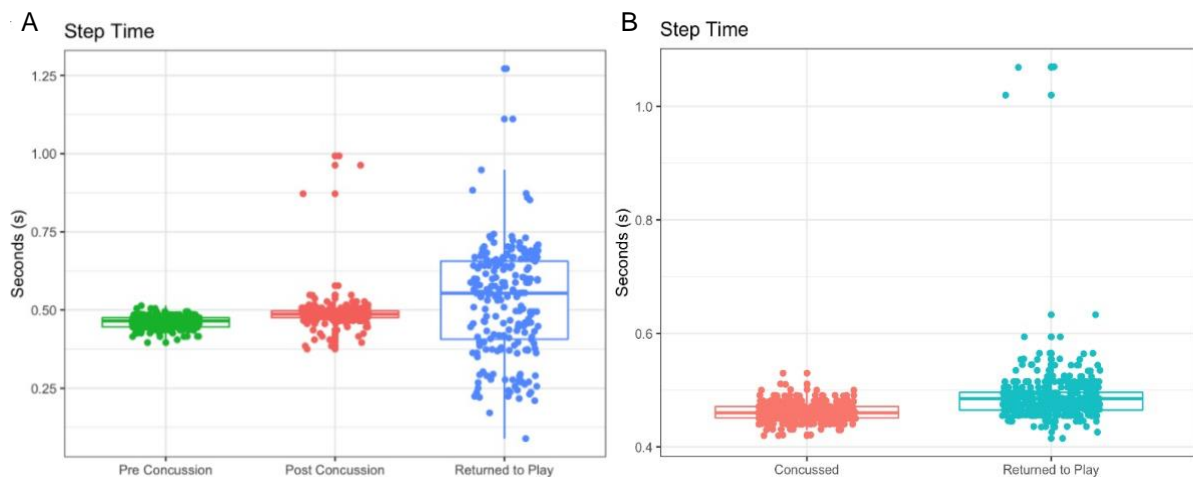
Impact

1. **Powell D**, Stuart S, Godfrey A. “Sports related Concussion, contrasting approaches”: *British Journal Sports Medicine Blog*, January 2021
2. Martin M, Bearne L, James A, Choyce J, **Powell D** . [“Telehealth in Physiotherapy”](#). *Chartered Society of Physiotherapy*, May 2020

Appendix 2. Ethics declaration, Participant information and Consent Sheet

Appendix 3. Copyright permissions to use full use of chapters

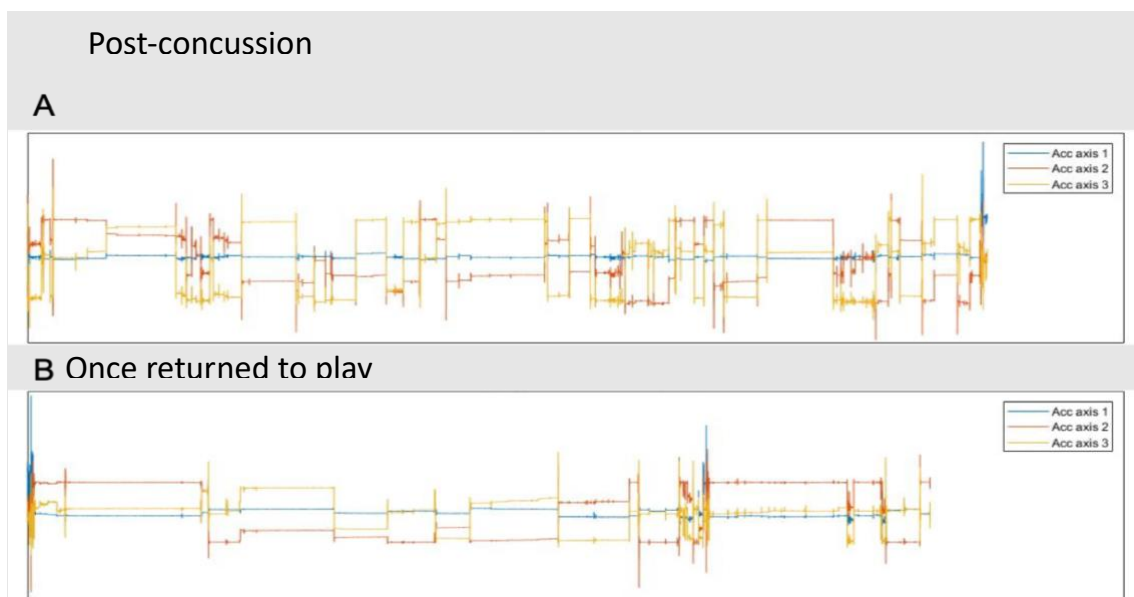
Appendix 4. Chapter 5 Supplementary Gait Data



(A) Supervised (laboratory) gait assessment (Two-Minute Walk Test); pre-SRC, post-SRC and RTP for step time. (B) remote gait assessment for step time

Appendix 5. Supplementary data for exploring sleep

Raw IMU accelerometer data were used to broadly examine and compare nocturnal/sleep activity at different times. Figure below shows notable differences between timepoints with greater frequency of movement as defined by the changing orientation of the accelerometer signal (e.g., axis 3 representing the traverse plane about the longitudinal axis within the IMU). This high-level visual examination suggests the participant had poorer sleep quality due to unsettled behaviour and changing from lying on right to supine to left postures, Contrastingly (B) shows far fewer periods of movement and longer periods of less sleep disturbance, potentially indicating improved sleep quality 1-month post-SRC.



Appendix 6. iOS SCAT5 app

Appendix 7. Sustainable healthcare: Considerations for integrating wearables into everyday practice

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