Assessing footwear in the presence of running-related injuries

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ABSTRACT

Despite the general acceptance that running-related injuries (RRI) are multifactorial, identifying specific risk-factors has been a prominent epidemiological research objective. For more than five decades, footwear has been a common variable among studies investigating the causal nature of running-related injuries. Several footwear characteristics (i.e. type, midsole properties, and comfort) have been implicated as beneficial or detrimental in the aetiology of such injuries. Reasons for these conflicting results could be attributed to the complexities of footwear design and use. Furthermore, the need for and utility of footwear measurements in research and clinical settings is unclear.

A recently developed systems-based theoretical model, the running-injury system, has suggested a paradigm shift to consider that injury is an emergent property of multiple factors (i.e. personal, social and environmental). Reducing the risk of injury requires understanding the structure and relationships between these factors and improving the functionality of the system’s components.

The footwear micro-system is a component of the running-injury system that has not previously been explored in the academic literature. Doing so involves addressing three main objectives: (1) identify areas in need of strengthening, (2) examine indirect effects of the footwear micro-system on running-related injuries, and (3) present novel interventions to prevent injury. Given these criteria, the current thesis aimed to adopt a systems-based perspective while answering five specific research questions:

1. What are the methods and tools currently used for assessing footwear on running-related injuries?

2. What factors influence runners’ footwear choices?
3. How do clinicians perceive footwear when assessing and treating patients with running-related injuries?

4. Is the footwear total asymmetry score tool (TAS) a reliable assessment of mediolateral asymmetry?

5. Is it feasible to conduct an observational study for determining the association between footwear asymmetry and running-related injuries (RRI) among runners?

Multiple study designs were used to answer these questions. A systematic review of the literature highlighted that current research procedures do not use consistent methods of assessing footwear characteristics (Chapter 3), ultimately limiting the evidence of the effects of footwear on RRI (Chapter 4). Qualitative research revealed runners’ behaviours towards their footwear selections are influenced by economics, other people and their own needs (Chapter 5). Chapter 6 determined that most clinicians have a person-centred approach when assessing and prescribing footwear among patients with RRI. However, one outlier clinician presented an objective footwear assessment tool which was carried forward in the subsequent Chapters. Chapter 7 determined that the total asymmetry score tool is a reliable footwear assessment tool for determining the mediolateral asymmetry at the rearfoot and forefoot of running shoes. The results of the feasibility study in Chapter 8, indicated conducting a full-sized prospective trial assessing the association of footwear Total Asymmetry Score tool (TAS) to RRI is not feasible in Dunedin, New Zealand. While the results of Chapter 8 are not ideal, this thesis contributes to an emerging body of knowledge utilising complex systems theory to complement traditional epidemiological approaches to better understand the influence of footwear on RRI.
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ABBREVIATIONS

ANOVA – Analysis of Variance
BD – Ben Daniel
BMI – Body Mass Index
CHOIR – Collaborative Health Outcomes Information Registry
COREQ – Consolidated criteria for Reporting Qualitative research
CR – Codi Ramsey
FPI – Foot Posture Index
GS – Gisela Sole
ICC – Intraclass Correlation Coefficient
LC – Lynne Clay
MDD – Minimal Detectable Difference
OSTRC – Oslo Sports Trauma Research Centre
PRISMA – The Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO – International Prospective Register of Systematic Reviews
RCT – Randomised Controlled Trial
REDCap – Research Electronic Data Capture
RRI – Running-related injuries
SEM – Standard Error of Measurement
STAMP – Systems Theoretic Accident Mapping and Processes
STROBE – Strengthening the Reporting of Observational Studies in Epidemiology
TAS – Footwear total asymmetry score tool
USA – United States of America
VAS – Visual Analogue Scale
PREFACE

As a young athlete, I was humbled to stand on top of podiums, knowing my moment of glory would be hung-up on the medal rack my dad had built out of old horse-shoes. I was also acutely aware of the chores – feeding cows and horses, stacking hay, or cooking dinner – that were waiting for me when I got home. Despite the gruesomeness, I loved growing up on a farm (or ‘ranch’ as we call it in Wyoming, USA), it made me tough, it taught me hard-work and it showed me freedom at its finest. It also taught me that with a relentless amount of resilience, I can accomplish anything.

During my final year of high school, and to my dismay, the pain in my knees and hips during running was debilitating. Regardless of how hard I pushed myself, I could not compete. My family had little money for health-care, so sitting in the frozen horse trough was often my best therapy. I have battled running injuries ever since. I have shamefully pushed my toddler home in his jogging-stroller, after turning back, because I could not run another block. I have cried in pain, mile after mile, during a half-marathon race. Even still today, my son (now 13-years-old) runs ahead and waits for me to catch up and will graciously walk me home with his arm wrapped around my waist. These moments are frustrating, especially given my self-proclaimed toughness.

Unfortunately, my story is not unique – except perhaps, the horse-trough ice baths. Running-related injuries are not shy. Indeed, to experience them for years on end is distressing and motivating at the same time. As I watch my talented young son build his own endurance and determination, it breaks my heart to know that he will endure injury. It is my hope that his injuries are minimal and short-lived. This journey has given me a voice, and I maintain that the concepts in this PhD project will be further developed, and someday running-related injuries will be prevented.


1 CHAPTER 1: INTRODUCTION

1.1 Chapter Overview

Chapter 1 is the introduction to this thesis. It explains the background, framework and aims of the research completed for this PhD project. The Chapter concludes with the research pathway which demonstrates the need and use for an objective footwear assessment tool to better understand the role of footwear in treating and preventing running-related injuries (RRI). For the purpose of this thesis, the terms ‘footwear’ and ‘shoes’ are used interchangeably and unless otherwise indicated, represent footwear designed for running.

1.2 Reasons for this research

1.2.1 The value of running

Ancient stories tell of a Greek messenger, Pheidippides, who collapsed from fatigue after running 26.2 miles to Athens to deliver news about the arriving Persian ships in an attempted attack on the Greeks [1, 2]. The Athenians victory over the Persians in the Battle of Marathon, is often credited to Pheidippides’ super-human efforts and abilities to run such an incredible distance and warn the army. The legend of Pheidippides also inspired the first modern-day, marathon event during the 1896 Olympic games [1, 2].

Running is among the most common forms of physical activity and is a required aspect of many sports (soccer, basketball, rugby etc.) [3, 4]. Recreational running has increased in popularity with record entrants in organised international and local events [5, 6]. Indeed, running is often done for personal reasons such as: connecting to nature, maintaining fitness
and health, or enjoyment [7, 8]. People may also run for reasons of survival, hunting and gathering [9], or as a commute to save money and reduce carbon footprints [7, 8].

Running has been attributed to increased aerobic fitness, cardiovascular function, metabolic fitness, cardiac adaptation, muscular performance and postural balance [10]. Running, even at slow paces (<10 kilometres per hour) and for less than 50 minutes per week (10 minutes per day for five days), can reduce the risk of cardiovascular disease and all-cause mortality by up to 45% in runners, when compared to non-runners [11]. Additionally, reductions in body mass, body fat, resting heart rate and triglycerides can be achieved after one-year of regular running [12]. Running also provides psychological benefits such as improved mood [13] and reduced stress [14].

In New Zealand, over 19% (635,000 people) of adults choose to run or jog, making it the sixth most common activity behind walking (60%), swimming (30.2%), cycling (24.8%), gym exercises (22.4%) and fishing (19.5%) [15]. Compared to the 2007-08 New Zealand activity participation data, running/jogging has seen the second largest increase (2.7%), only slightly behind cycling (up 3%) [15]. These data suggest more people are taking advantage of the highly accessible activity to improve health, well-being and quality of life.

1.2.2 Impact of running-related injuries

A recent systematic review found limited evidence to support age, sex, height, or experience as risk factors for RRI [16]. However, previous reports have indicated that RRI can occur at a rate of up to 33 injuries per 1000 hours of training [17] and the incidence rates range from 18.2% to 92.4% [16, 18, 19]. Reasons for this wide range of incidence rates have been attributed to a lack of standard definitions for RRI and running experience [20, 21], and risk factor measurement tools [22, 23].
While it is difficult to determine specific risk factors for RRI, specific injury or injury locations are more concisely agreed upon in the literature. The knee is the most common location of injury [19] and medial tibial stress syndrome is the most common injury, affecting up to 50% and 20% of runners, respectively [24]. Disruptions to regular running routines due to injury have been shown to significantly increase tension, anxiety, depression, confusion, anger and hostility among injured runners [25]. Further, previous RRI is a primary risk factor for acute injuries –such as: muscle/tendon and ligament strains or tears–, or chronic conditions –including overuse injury and osteoarthritis– [26s].

Injury is one of the top reasons novice runners quit running and become physically inactive [27]. A report from 2013 data, estimated the global cost of physical inactivity at 53.8 billion (INT$) [28]. Direct and indirect costs specific to RRI have only been established in the literature for Dutch novice runners training for a 5k event [29], and Dutch trail runners [30]. The burden of a single RRI in the Netherlands ranges from €83.22 to €174.40, representing about 0.2% to 0.4% of all annual sports injury costs. Although not reported in academic literature, the burden of RRI in New Zealand represents NZD $6.8 million (nearly 1%) of the annual costs associated with all sports injuries [31].

1.2.3 State of RRI research

It has long been recognized that RRI are multifactorial [32-38] and are the result of repeated micro-traumas to the musculoskeletal structures used during repetitive movements [39, 40]. Broadly speaking, RRI’s have been attributed to: personal factors (age, sex, height, weight, BMI, hormones, personality type, stress), lifestyle and health factors (diet, alcohol consumption, use of oral contraceptives), and running/training factors (distance, duration, intensity, frequency, terrain/surface, speed/pace, footwear and insoles, previous injury and
participating in other activities) [17-19, 29-30, 46]. However, despite the body of work
describing RRI and the plausible risk factors, two prominent issues persist in the research and
clinical settings. First, RRI still affect large proportions of runners each year. Second, current
hypotheses and research aims are centred on identifying risk factors associated to the
individual runner.

In particular, footwear has gained much attention as a risk factor because it is easily
manipulated in research settings and is an inexpensive clinical intervention [41, 42]. Indeed,
much research has been conducted to determine how footwear may be influencing RRI [43-
50]. This approach follows traditional reductionist methods or ‘black box epidemiology’ which
works backwards from injury, attempting to expose a one-to-one relationship between risk-
factor and injury [51, 52]. This is problematic because it suggests risk of RRI can be reduced
through modifying runners behaviours (i.e. choosing the ‘best’ footwear). As a result of this
black-box epidemiological thinking in the current footwear and RRI research, two conflicting
paradigms have emerged: the motion-control paradigm and the minimalist footwear trend.

1.2.3.1 Motion control paradigm

Early footwear research (1970-1995) analysed the kinetic and kinematic variables of the foot
and lower leg and their biomechanical relationship to RRI [41]. Concepts that injury may be a
result of high impact forces or excessive rearfoot motion led to the development of motion-
control running shoes equipped with thick cushioned heels and stability devices [41, 42, 53,
54]. Some studies found these motion-control features to be effective at reducing ground
reaction forces [55, 56] and lower-leg and foot movements [57], while others observed
increases in hip adduction [58, 59] postural instability [50, 60] and medial knee adduction [61].
It was later recognised that in order to reduce injury, the foot need to be classified (i.e. supinated, pronated or neutral) and matched to the corresponding footwear type (i.e. cushioning, motion control or stability, respectively) [42, 62]. These claims were critically evaluated in three large RCTs of military populations conducted by Knapik and colleagues [63-65]. Results of all three studies indicated matching footwear type to foot posture had no influence on injury rate. However, in a recent, study, Malisoux et al. (2016) found that providing motion-control shoes to runners with pronated feet reduced the risk of injury (HR=0.55; 95% CI 0.36 – 0.85) [66]. The differences between studies occurred due to study design, population and footwear characteristics. Malisoux et al. (2016) were able to blind the participants to the type of shoe they received and focused on recreational runners [66]. Whereas, the military studies by Knapik et al. (2009, 2010) did not de-identify the footwear, and the military recruits participated in high-training loads and activities other than running [63-65]. It is also possible that there are inconsistencies in the nomenclature of footwear characteristics between different brands/manufacturers [65, 66].

1.2.3.2 The minimalist trend

A series of published research and subsequent discoveries about our ancestors were the catalyst for the minimalist trend observed over the past 15 years. Studies on the evolution of human bi-pedal gait revealed humans have been running for nearly 2 million years [9]. Additionally, the footwear used by these early ancestors was fashioned from sagebrush and rope and was merely for protection [67]. Elite athletes – particularly, runners attending the University of Oregon, USA, under the direction of Coach Bill Bowerman – were training barefoot and seeing great success [68]. These events influenced author and story-teller Christopher McDougall to release a best-selling book Born to Run [69] in 2009 which highlights
a tribe of Native people deep in the deserts of Mexico, who run impressive distances and speeds, without injury, and while barefoot [69].

In 2010, a paper published in *Nature* identified biomechanical differences between runners in traditional style footwear (cushioned, motion-control, stability) and barefoot runners [70]. The study revealed that barefoot runners are more plantar flexed during the ground contact phase, which increases the hip and knee flexion, and reduces the collision forces applied to the body [70]. These mechanics were speculated to be reminiscent of early *homo erectus* gait patterns and have been publicised as ‘natural’ [69, 70]. The natural gait pattern, described as forefoot running, was observed in both acute [71] and habitual [72] barefoot runners, indicating that when shoes are removed, the body reverts to its natural or ancestral gait habits.

The idea of preventing injury by running with a forefoot gait pattern resonated with many runners around the world and a massive trend soon followed [68]. While barefoot running was seen as natural method of running, it was not feasible for most runners, as they believe they are at an increased risk of acute injuries (i.e. cuts, abrasions) from manmade surfaces (i.e. concrete, asphalt) [73]. Therefore, footwear companies (most notably, Nike Inc., Beavertown, OR., co-founded by Bill Bowerman), developed a new style of shoe, the minimalist shoe. The minimalist shoe was designed and marketed to allow runners to mimic natural, barefoot motions (i.e. Nike Free), while protecting the plantar surface of the foot. This minimalist style of running appealed to more people than barefoot running [73] and multiple companies soon emerged offering the general public a wide range of minimalist footwear.

As the popularity of forefoot running in minimalist footwear increased, clinicians began to see different kinds of RRI including: meta-tarsal stress fractures, plantar fasciitis, and Achilles tendon strains and ruptures [43, 74-76]. These injuries presented a whole new set of research questions and research aimed to determine which style of minimalist footwear is
best suited for running [47, 49]. Perhaps unsurprisingly, conflicting results have been published [43, 47, 76-78]. However, methodological limitations of well-designed studies have led to guidelines for safe transitions to minimalist footwear [79] and a consensus definition and rating scale for minimalist footwear [22]. Not only do these developments provide external validity for studies, but also they are a step forward in an ecological approach to the multifactorial understanding of RRI [80-86].

1.3 Systems-based research

Systems-based research is a sub-discipline in the field of systems ergonomics. It emerged partly from General Systems Theory [87], and has been refined in the fields of engineering and organisational safety [83]. A number of recognized principles guide systems-based research [88-90], which ultimately suggest: adverse events emerge from complex decisions, actions and interactions between multiple related and non-related factors [83]. This violates typical regression model frameworks as seen in traditional epidemiology research, in which discrete variables are studied under ideal circumstances and effects are attributed to specific errors [91]. Systems-based research is also counterintuitive to implementing treatment and prevention strategies, in which traditional behaviour change modifications start with the individual in possession of the risk-factor and are generalised to other individuals with the same traits [91].

Systems-based research aims to understand and explain the social, political, and economic factors underpinning complex phenomena (e.g. aviation accidents, spread of HIV) [92]. Systems-based research operates under the assumption that multiple human and non-human factors are interacting in a dynamic and complex environment to influence individual behaviours [93]. For example, the nuclear Chernobyl disaster resulted from a combination of
reduced operating power, a disabled safety system, operator actions, and the complexity of the nuclear reactors [94, 95]. The nuclear explosion cannot be attributed to a single action or sequence of actions, but rather a culmination of several chance and non-chance events [95].

A benefit of systems-based research is the ability to construct organisational safety with a top-down approach [91]. To illustrate, during World War II and the Korean War, government officials ‘blamed’ the alarmingly high incidence of plane crashes on human-error, bad personalities or task incompatibility [96]. However, an external researcher identified that the design of the pilot’s cock-pit required time-intensive information processing and multiple complicated tasks to control the plane [96]. When the combat planes were re-designed with multi-function pilot control-sticks, allowing intuitive operation of the plane, fatal crashes decreased to 5%, a massive improvement from the previously designed planes [96].

Systems-based research has also been used to construct safety models in the health sector. When looking at endemic disease prevention (e.g. HIV/AIDS, hepatitis and tuberculosis) individual behaviour change interventions have failed to reduce risk and transmission rates [97]. Only through collaborative social and structural approaches has the public become aware of not only the consequences of disease, but also how to avoid exposure [97].

The structure of a multifactorial sports injury is ideally suited for systems-based analysis [83]. In fact, ecological injury models have been conceptualised as early as 1970 [98]. More recently, Meeuwisse et al. (2007) visualised sports injury in a dynamic and recursive model in which injured athletes recover and adapt to varying risk factors in order to resume participation [99]. However, implications from the sports injury model by Meeuwisse focus on the individual athlete and identifying risk factors [99], while systemic and interpersonal factors are absent [83]. These are limitations which have challenged ergonomic researchers to apply
the systems-based models native to industrial and health disciplines, to the context of specific sports injuries (e.g. running) [80, 83].

1.3.1 The running-injury system

While most ergonomic models are traditionally used to explain safety critical domains (e.g. nuclear industry, transportation, and health care systems [100-102], Hulme (2017), recently completed a PhD thesis which he applied a systems-based model to the context of RRI in Australia [103]. After evaluating multiple potential models, the Systems Theoretic Accident Mapping and Processes (STAMP) model was ultimately adapted because it can reflect the hierarchy and relationships present between multiple actors within the system [81]. Members of the running-injury system, as defined by Hulme (2017) [81], are organised into five levels: 1) Parliament and legislatures; 2) Government agencies, sporting associations, funding and research organisations-which are also governed by international bodies; 3) General service and healthcare providers; 4) Running management, supervision and injury prevention; and 5) The runner and the running process [81] (Figure 1).

The purpose of the running-injury system is to visualise the structure and understand RRI from a wide-angle lens [81]. The running-injury system acknowledges that control structures (i.e. government policies, product development procedures, culture) may influence the health and safety of runners [81]. The key components of the running-injury system model are its ability to identify the irreducible properties and relationships of different hierarchies and describe the people or organisations that reside within the system [81]. This structural understanding can then be used in parallel with traditional epidemiological methods to develop strategies to treat and prevent RRI [81].
In summary, systems-based thinking requires complementary epidemiological research that addresses three main research objectives: (1) identify areas in need of strengthening, (2) examine indirect effects of the system on injury and (3) present novel injury prevention interventions [81, 83]. Although the current running-injury system model is valid, it does not explicitly suggest areas in need of improvement [81]. Instead it encourages scientists to examine the system and initiate new ideas and research that contribute to injury prevention strategies [81, 104]. Given the past issues and current progress in footwear research, focused attention to this area is justified.

1.3.2 The footwear micro-system

Within each of the levels of the running-injury system exists several micro-systems which operate under their own sets of structures and hierarchies [81]. The structure of the footwear micro-system has not yet been developed –and requires an entirely separate body of work. However, it is hypothesized that the relationship between RRI and footwear is manipulated by entities such as: design and manufacturing procedures, federal regulations on imported goods, research funding and output, health care and sporting services, footwear retailers, clinicians, coaches and other runners (Figure 1). The influences from these factors can impact individual behaviour and decisions that may manifest into RRI [81].
Running Injury System (Hulme, 2017)

Figure 1: The running-injury system (adapted model from Hulme, et al. 2017) and the proposed interaction of the footwear micro-system (contained in red dotted line)

To address the potential influence of the footwear micro-system on RRI the objectives for improving the running-injury system are modified as follows:

- Identify gaps in the literature where footwear research could be improved
- Examine the indirect constraints or influences of footwear on members (i.e. runners and clinicians) of the system
- Present potential intervention strategies to prevent RRI

Indeed, addressing these objectives requires epidemiological methods. Furthermore, a criticism of theoretical systems-based models in sports science is the gap between research and practitioner [105]. It is contended here that, in addition to the theoretical approach, practical tools are needed to improve this area of concern within the system. Members (e.g. researchers and clinicians) of the footwear micro-system could benefit from practical and objective footwear measurement techniques to make informed decisions about the quality
and condition of footwear. These measurements can provide feedback to key stakeholders regarding the overall functioning of the footwear micro-system. The measurements can also inform intervention procedures or control strategies employed by other members of the running-injury system that can improve the health and safety of the runner.

1.3.2.1 Studies of footwear properties

Past studies have used traditional black-box epidemiology (i.e. cause and effect) to link footwear properties to injury. In determining the shock-absorbing capabilities of footwear cushioning, Hamill et al. (1988) [106] evaluated the in-vivo loading during gait. They found that as footwear cushioning properties deteriorate, impact and loading forces increase. This has been supported by several other studies [60, 107-111]. Indeed, high ground impact and loading forces are the foundation of the motion-control paradigm and findings from these studies further support the design, manufacturing, and use of motion-control footwear. However, a major shortcoming of these studies is that the link between footwear material composition and kinematic variables is not supported by direct measurements of footwear degradation, but rather indirectly through use or tracking of distance.

Veredejo et al. (2004) [112] directly evaluated the effects of footwear degradation of ethylene vinyl acetate (EVA) foam in footwear on plantar pressures among runners. The authors examined samples of new and used EVA material under a scanning electron microscope and found increased planar pressures among participants after 500 km of use and structural damage to the EVA (wrinkles and holes) after 750 km of use. Similarly, Lippa et al. (2014) [113] performed mechanical ageing on footwear and found a decrease in net displacement, energy absorbed, percent energy absorbed and peak impact force of EVA foam after 100 miles (162 km) of simulated running. Additional studies have found similar results.
after 500 km [114] and among different materials [115]. However, these studies do not include human variability and due to the multiple designs and differences in footwear manufacturing and material testing processes, it is difficult to generalise these findings across shoe types or provide feedback to the footwear micro-system.

In more recent years, measurements of footwear characteristics such as midsole thickness, heel-toe-drop and flexibility have been studied in relation to performance and biomechanical variables [57, 116-121]. Studies have struggled to reproduce similar results, leaving the literature with a wide scope of possible interactions between footwear characteristics and various outcome variables. Additionally, the minimalist and barefoot paradigm have influenced a comparison of conditions (barefoot vs shod) and conclusions often imply risk or protective factors of one of the conditions [74, 122, 123]. Only a handful of studies have evaluated the effects of footwear characteristics on RRI and these are presented in Chapter 3. Indeed, prominent limitations of these studies are centred around the variability and operational definitions of footwear characteristics and the external validity and applicability to the footwear micro-system. Therefore, requiring alternative proposals for measuring footwear that can be applied to footwear of varying degradation, composition, or finite characteristic but also reflects the influence of footwear on the individual runner.

1.3.2.2 A novel perspective: Measuring footwear mediolateral asymmetry

Previous research completed as part of a PhD project from the University of Otago, School of Physiotherapy developed a method to objectively measure mediolateral asymmetry present in footwear [124]. The total asymmetry score tool (TAS) was used as part of clinical practice and was evaluated under controlled laboratory settings to determine if mediolateral asymmetries in footwear had negative effects on kinematic variables and performance. When
assessing the asymmetry of nearly 300 shoes, more than half (62.6%) of the inner-, mid-, and/or outer-soles were skewed (medially or laterally) by up to 8 mm. Further, participants had significantly decreased repetitions of heel raises (p < 0.001) and slower stabilisation times with small (1 mm to 3 mm) mediolateral disturbances to the foot-ground interface [124].

Upon undertaking the current PhD project, the TAS tool was presented as a novel tool that was virtually unused in research of RRI. Considering that running includes dynamic single-legged stance and balance, it is possible that mediolateral asymmetry affects runners. The asymmetric design of some footwear (i.e. motion-control shoes) could inhibit the runner’s movement and performance. Indeed, as the shoe degrades from use, the asymmetry may increase, further affecting the runner.

Assessing mediolateral asymmetry as part of a systems-based perspective allows members of the system (researchers, clinicians and runners) to be aware of the inherent asymmetry by design and monitor the changes to asymmetry over-time. This information can be translated to upper hierarchies that may control the design of footwear. Additionally, the asymmetry scores can be used to inform interventions (i.e. balance footwear to a symmetric condition). However, the plausible roles of footwear asymmetry at the individual and system-wide levels are only speculated.

Ultimately, a well-organised system contains high-functioning micro-systems that contribute to the synergy and connectivity of the system as a whole [125]. The running-injury system model is in its infancy and developing policy and implementing system-wide changes is not yet possible [83, 92]. However, given that using epidemiological methods are required to further explore the footwear micro-system and the practical use of objective footwear measurements, the course for this PhD project is evident.
1.4 Research pathway

1.4.1 Research Aim

The purpose of this PhD project is to assess the need for and utility of footwear measurements in research and clinical settings, and within the context of the footwear micro-system, to treat and prevent RRI.

1.4.2 Research Questions

To address the above aim, the primary questions addressed in this thesis are as follows:

1. What are the methods and tools currently used for assessing footwear on running-related injuries?
2. What factors influence runners’ footwear choices?
3. How do clinicians perceive footwear when assessing and treating patients with running-related injuries?
4. Is the footwear total asymmetry score tool a reliable assessment of mediolateral asymmetry?
5. Is it feasible to conduct an observational study for determining the association between footwear asymmetry and RRI among runners?

1.4.3 Overview of Thesis Chapters

This PhD project is presented in nine chapters (Figure 2). The research conducted in Chapters 3 and 5-7 were done so in parallel and therefore do not inform one another, but rather address the research question of this thesis from different angles. Chapter 2 provides selected
background information for Chapters 3 and 4. Further Chapter 8 uses the footwear assessment tool described in Chapter 7. Six chapters (Chapters 3-8) are written as manuscripts which are either under revision or will be submitted for publication. The chapters have been organised to ensure the flow of this thesis represents a standalone body of work.

Chapter Two presents selected footwear measurements tools currently available in RRI research. This provides the background and context for the following systematic review presented in Chapters 3 and 4.

Chapter Three presents the first part of the systematic review of this thesis. The Chapter evaluates of the current methods used to assess footwear characteristics among studies of RRI. Information from this chapter was presented in Cambridge, New Zealand at the “2017 Sport and Exercise Science New Zealand Annual Conference” and in Dunedin, New Zealand at the “University of Otago Graduate Research Symposium” [126, 127]. A manuscript of this Chapter is currently under review with Journal of Sport Sciences.

Chapter Four is a secondary assessment of the articles obtained in Chapter three. A pragmatic approach is used to evaluate level of evidence regarding the association between
footwear characteristics and RRI. Combined with Chapter 3 these chapters highlight a prominent gap, in need of strengthening, in the footwear micro-system. A manuscript from this Chapter will be submitted to Physical Therapy Reviews during the publishing bursary period.

**Chapter Five** describes a qualitative study conducted to identify the factors that influence runners’ footwear choices. This Chapter explores an area of RRI research that has received little attention in the literature: behavioural science. This Chapter contributes to the footwear micro-system by exploring indirect effects of footwear on runners’ behaviours. This Chapter will be presented at the “2018 Sport and Exercise Science New Zealand Annual Conference” and submitted as a manuscript to the journal of Qualitative Research in Sport, Exercise and Health.

**Chapter Six** is a second qualitative analysis focusing on the clinician’s perspectives of footwear as part of the treatment and management of patients with RRI. Again, this Chapter explores an under-studied area of the literature, assessing the clinicians’ perspectives on this topic. This Chapter also contributes to the footwear-micro system by exploring the indirect effects of footwear on clinicians’ behaviours. Additionally, this Chapter highlights the need for objective footwear measurements in clinical settings. An abstract of this Chapter has been submitted for the “2018 Physiotherapy New Zealand Annual Conference” and will be submitted as a manuscript to the journal of Physical Therapy.

**Chapter Seven** presents the essential psychometric properties (within-rater, between-rater, between-day reliability) of the total footwear mediolateral asymmetry score tool (TAS) (described by Sole, 2010) for assessing footwear mediolateral asymmetry [128]. Two novice and two expert raters— including the tools developer— independently assessed the asymmetry of ten different non-paired shoes. This Chapter contributes to the footwear micro-system by presenting a reliable tool that can be used by clinicians when assessing footwear. A poster
containing the results of the reliability of the TAS was presented in Salt Lake City, USA at the *Gait and Clinical Movement Analysis Society Annual Conference* [129] and was accepted for publication by *Footwear Science* [130].

**Chapter Eight** describes a feasibility study for assessing the effects of footwear asymmetry on RRI. This Chapter addresses the fifth and final research question for this PhD project (See section 1.4.2) and presents a novel perspective for addressing the effects of footwear on RRI. Results of this study were presented in Brisbane, Australia at the “2018 Exercise Science and Sport Australia Annual Conference” as a poster. A manuscript will be submitted for publication to *JOSPT* during the publishing bursary period of this thesis.

**Chapter Nine** is the final chapter of this thesis and presents an overview of the results of this PhD project. The Chapter also discusses two main topics (i) the role of the TAS in the footwear micro-system and (ii) the future research directions in the footwear micro-system. The chapter concludes with the strengths, limitations and contributions to knowledge of the current PhD project.
2 CHAPTER 2: LITERATURE REVIEWS

2.1 Chapter Overview

The Chapter presents an overview of selected available footwear assessment tools. It provides the background and introductory material for Chapters 3 and 4 which systematically reviewed the methods and tools used (Chapter 3) and the association (Chapter 4) between footwear characteristics among studies of RRI.

2.2 Tools for assessing footwear

Until recently, assessing footwear characteristics has been generally overlooked in studies of running related injuries (RRI) [22, 131]. Researchers and clinicians have adopted multiple ways of assessing footwear and although numerous footwear assessment tools are available [23, 132-135]. Many footwear assessment tools are designed for specific populations (diabetic, children etc.) or lack necessary psychometric properties [132, 134, 135]. As described in Chapter 1, despite a growing number of experimental and observational footwear studies, the potential benefits of monitoring footwear are yet to be determined but could assist in developing evidence-based guidelines for use, injury prevention and replacement.

Examining the relationship of footwear on RRI is complicated by factors such as: the type and definition of footwear, the validity and reliability of specific footwear measurements, the marketing and quality of footwear technologies, and subjective characteristics (e.g. shoe fit). Additionally, practical issues involving the measurements of footwear between and/or within studies and participants limit thorough conclusions and generalisability [48-50, 131, 136-139]. Among the tools available for assessing footwear characteristics, only three have
been shown to be valid or reliable for use with multiple footwear designs and/or populations [22, 23, 140]. The footwear comfort tool [140], footwear assessment tool [23] and the minimalist index [22] are described below.

### 2.2.1 Footwear Comfort Tool

The footwear comfort tool [140] was developed to provide clinicians with a standardised and objective assessment of patient’s custom insoles/orthotic devices. The tool uses visual analogue scales (VAS) to assess eight different comfort domains: overall comfort, heel cushioning, forefoot cushioning, medio-lateral control, arch height, heel-cup fit, shoe heel width, shoe forefoot width and shoe length. Within-subject repeatability of footwear comfort was high (ICC=0.799) for 67% of the participants. Further, between-test variability was inversely related to an increasing number of footwear comfort test sessions.

While the footwear comfort tool adequately assesses the subjectivity of footwear comfort, the main limitation is that comfort has not been correlated to physical footwear characteristics. This requires clinicians and researchers to rely on the patient/participant having high foot sensitivity and being confident using a VAS [140]. Additionally, within-rater reliability has been observed as poor (P < 0.7) [141]. The authors of this tool suggest using a control shoe, testing participant repeatability, and multiple testing sessions to reduce variability of comfort results [140].

### 2.2.2 Footwear Assessment Tool

A six-item comprehensive tool was developed by Barton et al [23]. The tool assesses 16 continuous and 27 categorical measurements of: fit, general features, general structure,
motion control properties, cushioning and wear patterns. Within-rater and between-rater agreement was excellent (ICC > 0.80) for 10 (63%) of the continuous measurements and substantial (Kappa 0.60 – 0.80) to excellent (Kappa > 0.80) for 24 (89%) of the categorical measurements. This tool is useful on a variety of populations and footwear and has been highly cited in research areas of foot disease (diabetes, gout) special populations (children, elderly) and various shoe types (high heels, flip flops, diabetic footwear) or biomechanical outcomes. However, it has received relatively little attention in the scientific literature of RRI. In a recent search of the 101 articles citing the footwear assessment tool (Google Scholar, September 9, 2018), only 29 articles appeared when adding a filter for the words “running injury”. Among these 29 articles, only three [142-144] actively used the tool, in-whole or partially, when evaluating footwear among runners. When consulting the lead author of the footwear assessment tool on this issue, Dr Barton suggested the tool may be absent from research on RRI due to several reasons including: improvements to the tool are needed, awareness of the tool, and research-knowledge translation (personal email with Dr Christian Barton). It is also possible that the tools length and time required to assess all footwear characteristics deters researchers and clinicians from using the tool in a pragmatic manner. However, since the reliability of each item in this tool was assessed, it is possible for researchers and clinicians to use the tool in part.

2.2.3 Minimalist Index Rating Scale

The most recent footwear assessment tool in the literature is a rating scale for minimalist shoes [22]. Prior to developing the tool, the authors also conducted a Delphi study to develop a consensus definition of minimalist footwear. Ninety-five percent of the experts included in the Delphi study agreed upon the following definition of minimalist footwear:
“Footwear providing minimal interference with the natural movement of the foot due to its high flexibility, low heel to toe drop, weight and stack height, and the absence of motion control and stability features” [22]

The tool assesses five characteristics using a VAS: mass, flexibility, heel-toe drop, stack height and motion control/stability devices. Subsequently, the ratings from the five footwear characteristics are collated into a single minimalist index rating, ranging from 0-100. Excellent within- and between-rater reliability (ICC >0.80) was found for the total minimalist index score and for four of the subscales (Gwet’s AC1 = 0.82-0.99) and good between-rater reliability (Gwet’s AC1 = 0.73) for identifying motion control/stability technologies. One significant benefit of the minimalist index tool is that it provides a rating for all types of athletic footwear, with higher scores indicating higher degrees of minimalism. An inverse relationship for decreased foot inclination, peak patellofemoral joint force, and greater step-rate has been shown with increasing minimalist index scores [44]. However, the tool does not provide distinguishing thresholds to separate various shoe types.

2.3 Conclusion

In summary, there are three main footwear assessment tools available in the literature that evaluate a variety of footwear characteristics. Strengths of the tools are the: associated validity and/or reliability ratings for each tool. The primary weakness of the tools described above is that they each use subjective assessments when evaluating footwear.
2.4 *In the next chapter*

The following chapter builds on the current knowledge of three main footwear assessment tools. It systematically evaluates the RRI research to identify how footwear characteristics are assessed among studies of RRI.
3 CHAPTER 3: RUNNING-RELATED INJURIES: HOW ARE FOOTWEAR CHARACTERISTICS ASSESSED?

3.1 Chapter Overview

Chapter 2 identified selected footwear assessment tools available in the literature and highlighted the strengths and weaknesses of each tool. Given their lack of use in research of RRI, a further analysis of the tools used to evaluate footwear in studies of RRI is justified. To ensure a full-search of possible footwear assessment tools used in the literature, a systematic search and review was required. The aim of the current Chapter was to systematically evaluate the tools used to assess footwear characteristics in previous RRI research. For the purpose of this Chapter, the term ‘footwear assessment tool’ or ‘tool’ refers to any subjective or objective assessment or reporting of footwear characteristics.

3.2 Method

3.2.1 Design

The Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) has been followed to report this review [145] (Appendix 1). The review protocol was registered on the International Prospective Register of Systematic Reviews (PROSPERO) on March 15, 2017 and updated on September 1, 2017 (Registration Number 42017059480).
3.2.2 Electronic search

An electronic search strategy (Appendix 2) was developed with a health-sciences librarian to identify relevant articles for this review. Five online databases (EMBASE, Medline, Science Direct, Scopus and Web of Science) were searched from inception to September 4, 2017. Email alerts were established from each of the databases to ensure new articles matching the search terms were screened and included when eligibility criteria were met. Titles retrieved from the systematic search were exported and saved into a reference management software (EndNote X7, Thomson Reuters, Toronto, Ontario). After removing duplicates, two reviewers independently screened titles and abstracts according to the inclusion criteria. A third reviewer was consulted when a consensus decision could not be met.

3.2.3 Eligibility criteria

Randomised control trial (RCT), prospective, retrospective, or clinical case studies that assessed footwear in the presence of running-related pain or injury among adult runners and published in English were included in this review. Studies assessing footwear characteristics or type as an intervention, or as a risk factor for running-related injury or pain were included. Participant age, sex, running experience or injury profile were not restricted in this review.

Studies were excluded if they evaluated footwear not intended for running (i.e. dress shoes, high-heels) or orthotic devices (custom or off-the-shelf) intended to alter body positions and movements. Studies were excluded if they evaluated the effects of footwear on only running biomechanics, performance or involved activities other than running.
3.2.4 Data extraction and quality assessment

The PhD candidate extracted information from each article describing the study, any footwear characteristics including, but not limited to: type, brand/model, heel-toe drop, midsole density, midsole material and comfort. Data was extracted regarding any footwear assessment tools or methods used to evaluate and determine the characteristics. Initially, the validity and reliability of the assessment tool and/or assessor was not extracted, however, we found that this information is valuable to the outcomes of this review and is therefore included. Sample size, participant characteristics, and intervention variables were also extracted. Since this review is establishing methods of reporting, authors were not contacted when sufficient data could not be obtained from the published report. In these cases, the term ‘not reported’ was indicated.

The methodological quality of included articles was independently assessed by two raters using a modified Downs and Black checklist [146]. Questions from the following subgroups were assessed: reporting (items 1-7, and 10), external validity (items 11-12), internal validity bias (items 14-18, and 20), selection bias (items 21-26), and power (item 27). Items 5 and 25 relate to confounding variables of which age, gender, and BMI were considered the most relevant confounders, as these factors have been found to correlate with running-related injuries [43, 147-149]. Studies that described all three confounders received a score of “2”, while studies with two or one confounder received a score of “1”. Item 27 was changed from a 0-5 scale to a dichotomous 0 or 1. Studies were assigned a “1” if the number of included participants met or exceeded the a priori power analysis. If a power analysis was not performed, the study received a score of “0”. For the purpose of this review, studies were considered to have a high methodological quality if they scored 17 out of 26 (65%) on the modified Downs and Black Quality Index. Agreement between raters was established using
Kappa statistics and interpreted as excellent (>0.80), substantial (0.60-0.79), moderate (0.40-0.59), or poor (<0.40)[150].

3.3 Results

3.3.1 Search results

An initial search returned 5,813 articles (Figure 3). After screening titles and abstracts, 21 full-text publications were assessed for inclusion. Six additional articles identified from the reference lists of the full-text articles were screened for eligibility. An updated search was performed on September 4, 2017 and found an additional 449 articles. Four full-texts were screened for inclusion, three were excluded. A total of 26 articles were included for qualitative synthesis in this review (Table 3.1). Of the included studies, twelve were randomised control trials (RCT), six were prospective, five were retrospective, and three were case studies. One study evaluated only females [50] and four studies evaluated only males [43, 75, 76, 151]. Studies took place in eight different countries including: Australia [48, 152], Canada [47, 50], Denmark[138], Italy [153], Luxembourg [43, 66, 139, 154], South Africa [155], United Kingdom [156], and USA [45, 63-65, 74-76, 78, 151, 157-159], [160].
Figure 3: PRISMA Flow Diagram of included and excluded studies
3.3.2 Study Characteristics

A total of 17,553 participants were represented in the studies: 9,705 were male and 4,724 were female, and 3,124 participants were not specified as either male or female. Mean ages ranged from 19.6 to 43.3 years and BMI ranged from 20.6 to 26.3. All the included studies examined novice or recreational runners, apart from six studies on military personnel [63-65, 156, 158] and one on competitive runners [156]. For descriptive purposes only, running-related pain or injury outcomes were presented as prevalence [45, 47, 50, 74, 75, 136, 153, 157-160], incidence [48, 63-65, 138, 139, 152, 155], risk ratio [48, 63-65, 76, 138], hazard ratio [43, 66, 154], odds ratio [156], time to injury [78], or pain reduction [151] [160] (Table 3.1)
Table 3.1: Characteristics of included studies

<table>
<thead>
<tr>
<th>Author, year &amp; location</th>
<th>Study design &amp; intervention</th>
<th>Participant characteristics</th>
<th>Footwear Characteristics Reported</th>
<th>Assessment tools/methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altman, A. R. et al. 2016 USA</td>
<td>Prospective (1-year) Barefoot/minimalist vs modern day shoes</td>
<td>n=201 (153/48) 18-50 (36.6) NR NR</td>
<td>Shoe type (minimalist, modern-day)</td>
<td>Custom definition of minimalist shoes Self-reported survey</td>
</tr>
<tr>
<td>Cauthon, D.J. et al. 2012 USA</td>
<td>Case Study Minimalist vs traditional</td>
<td>n=3 (1/2) 26-35 (30) NR Recreational</td>
<td>Shoel e type (traditional, minimalist)</td>
<td>PCECH definition for traditional shoes and custom definition for minimalist shoes Visual inspection</td>
</tr>
<tr>
<td>Cohler, M.H. et al 2015 USA</td>
<td>Retrospective (12-weeks) Minimalist</td>
<td>N=566 (400/166) NR NR Recreational/Competitive</td>
<td>Shoe type (Minimalist)</td>
<td>Self-reported survey</td>
</tr>
<tr>
<td>Di Caprio, F. et al. 2010 Italy</td>
<td>Prospective (5 years) superlight (&lt;250 g); light (250-300g); shock-absorbing (&gt;300g); spike shoes</td>
<td>n=166 (86/80) not reported (31.3) 24.5 Recreational</td>
<td>Shoe type (super light, light, shock-absorbing, spike shoes) Shoe mass</td>
<td>By measurements (mass) Not reported</td>
</tr>
<tr>
<td>Dubois, B. et al. 2015 Canada</td>
<td>RCT (16-week) Minimalist and traditional</td>
<td>n=24 (7/17) 18-55 (31.8) 24.5 Recreational</td>
<td>Shoe type (traditional, minimalist)</td>
<td>Brand/model Manufacturer definition</td>
</tr>
<tr>
<td>Author, year &amp; location</td>
<td>Study design &amp; intervention</td>
<td>Participant characteristics</td>
<td>Footwear Characteristics Reported</td>
<td>Assessment tools/methods</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Fuller, J.T. et al. 2017 Australia</td>
<td>RCT (26-week) Conventional vs minimalist</td>
<td>n=61 (61/0) 18-40 (27) NR Endurance runners</td>
<td>Shoe type (conventional, minimalist) Minimalist index Shoe mass Midsole thickness Heel-toe drop</td>
<td>Brand/model Manufacturer definition Minimalist Index tool Not reported Not reported Not reported</td>
</tr>
<tr>
<td>Gardner, L. I. et al. 1988 USA</td>
<td>RCT (12-week) Insole material (mesh vs polymer)</td>
<td>n=3025 (not reported) 18-41 (20.0) NR US Marine basic training recruits</td>
<td>Shoe age Shoe cost Materials (insoles)</td>
<td>Self-reported survey Self-reported survey Visual inspection</td>
</tr>
<tr>
<td>Giuliani, J. 2011 USA</td>
<td>Case Series Minimalist shoes</td>
<td>n=2 (2/0) 19-35 (27) NA</td>
<td>Shoe Type (minimalist)</td>
<td>Brand/model Manufacturer definition</td>
</tr>
<tr>
<td>Goss, D.L. et al. 2012 USA</td>
<td>Retrospective (16-month) Traditional, minimalist, barefoot</td>
<td>n=904 (450/454) 18-50 (37.8) NR NR</td>
<td>Shoe type (traditional, minimalist)</td>
<td>Self-reported survey</td>
</tr>
<tr>
<td>Author, year &amp; location</td>
<td>Study design &amp; intervention</td>
<td>Participant characteristics</td>
<td>Footwear Characteristics</td>
<td>Assessment tools/methods</td>
</tr>
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</tr>
<tr>
<td><strong>Grier, T.L. et al. 2016</strong>&lt;br&gt;USA</td>
<td>Prospective (1-year)&lt;br&gt;Traditional, stability, cushioning and motion control, and minimalist</td>
<td>n=1332 (1332/0)&lt;br&gt;18+ (25.3)&lt;br&gt;26.1&lt;br&gt;US Army brigade</td>
<td>Shoe type (traditional, stability, cushioning, motion control, minimalist)&lt;br&gt;Shoe age</td>
<td>Manufacturer definition for traditional shoes and custom definition for minimalist shoes&lt;br&gt;Self-reported</td>
</tr>
<tr>
<td><strong>Knapik, J.J. et al. 2009</strong>&lt;br&gt;USA</td>
<td>RCT (9-week)&lt;br&gt;Cushioned, motion control, stability</td>
<td>n=3119 (2168/951)&lt;br&gt;NR&lt;br&gt;NR&lt;br&gt;US Army basic training</td>
<td>Shoe type (cushioned, motion control, stability)</td>
<td>Manufacturer definition&lt;br&gt;Runners World definition&lt;br&gt;Brand/model</td>
</tr>
<tr>
<td><strong>Knapik, J.J. et al. 2010a</strong>&lt;br&gt;USA</td>
<td>RCT (12-week)&lt;br&gt;Cushioned, motion control, stability</td>
<td>n=1411 (840/571)&lt;br&gt;18-23 (19.9)&lt;br&gt;23.7&lt;br&gt;US Marine Corps basic training</td>
<td>Shoe type (cushioned, motion control, stability)</td>
<td>Manufacturer definition&lt;br&gt;Brand/model</td>
</tr>
<tr>
<td><strong>Knapik, J.J. et al. 2010b</strong>&lt;br&gt;USA</td>
<td>RCT (12-week)&lt;br&gt;Cushioned, motion control or stability</td>
<td>n=2702 (1979/723)&lt;br&gt;18+ (NA)&lt;br&gt;23.8&lt;br&gt;US Airforce basic training</td>
<td>Shoe type (cushioned, motion control, stability)</td>
<td>Brand/model&lt;br&gt;Manufacturer definition</td>
</tr>
<tr>
<td>Author, year &amp; location</td>
<td>Study design &amp; intervention</td>
<td>Participant characteristics</td>
<td>Footwear Characteristics Reported</td>
<td>Assessment tools/methods</td>
</tr>
<tr>
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</tr>
<tr>
<td>Malisoux, L. et al. 2015 Luxembourg</td>
<td>RCT (22-week) Use of multiple vs single pair of shoes</td>
<td>n=264 (195/69) 18+ (42.4) 22.9 Recreational</td>
<td>Number of shoes</td>
<td>Self-reported</td>
</tr>
<tr>
<td>Malisoux, L. et al. 2016b Luxembourg</td>
<td>RCT (6-month) heel-toe drop</td>
<td>n=553 (341/212) 18-65 (38.3) 23.9 Recreational</td>
<td>Shoe type (standard-cushioned) Heel-toe drop Midsole thickness Cushioning/hardness (midsole)</td>
<td>Brand/model Custom manufacturer prototype Not reported Not reported Not reported</td>
</tr>
<tr>
<td>Nielsen, R.O. et al. 2014 Denmark</td>
<td>Prospective (1-year) Neutral</td>
<td>n=927 (466/461) 18-65 (37.1) 26.3 Novice</td>
<td>Shoe type (neutral) Heel-toe drop Midsole thickness Material (midsole)</td>
<td>Brand/model Manufacturer definition Not reported Not reported Visual inspection</td>
</tr>
<tr>
<td>Author, year &amp; location</td>
<td>Study design &amp; intervention</td>
<td>Participant characteristics</td>
<td>Footwear Characteristics Reported</td>
<td>Assessment tools/methods</td>
</tr>
<tr>
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</tr>
<tr>
<td>Ostermann, K. et al. 2016 USA</td>
<td>Retrospective (1-year) Minimalist</td>
<td>n=47 (22/25) 18-65 (NA) 23.1 NR</td>
<td>Shoe type (traditional, minimalist)</td>
<td>Self-reported</td>
</tr>
<tr>
<td>Ryan, M.B. et al. 2011 Canada</td>
<td>RCT (13-week) Neutral, stability, motion control</td>
<td>n=81 (0/81) 18-50 (32.8) 23.5 NR</td>
<td>Shoe type (neutral, motion control, stability)</td>
<td>Brand/model Manufacturer definition PCECH Visual inspection</td>
</tr>
<tr>
<td>Ryan, M.B. et al. 2014 Canada</td>
<td>RCT (13-week) Neutral, partial-minimalist, and full-minimalist</td>
<td>n=99 (NA) 19-50 (33.7) 23 NR</td>
<td>Shoe type (neutral, partial minimalist, full minimalist) Midsole thickness Mass</td>
<td>Brand/model Manufacturer definition Not reported Not reported</td>
</tr>
<tr>
<td>Salzler, M.J. et al. 2012 USA</td>
<td>Case Series Minimalist shoes</td>
<td>n=10 (8/2) NR (43.3) NR Recreational</td>
<td>Shoe type (minimalist)</td>
<td>Custom definition in introduction, but no data reported in study</td>
</tr>
<tr>
<td>Salzler, M.J. et al. 2016 USA</td>
<td>Prospective (6-month) Transition from traditional to minimalist</td>
<td>n=14 (8/6) 22-41 (28.9) 22.7 NR</td>
<td>Shoe type (traditional, minimalist) Comfort</td>
<td>Brand/model Manufacturer definition Self-reported-Participant</td>
</tr>
<tr>
<td>Author, year &amp; location</td>
<td>Study design &amp; intervention</td>
<td>Participant characteristics</td>
<td>Footwear Characteristics Reported</td>
<td>Assessment tools/methods</td>
</tr>
<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Schwellnus, M.P. et al. 2006 South Africa</td>
<td>Retrospective (1-year) Shoes prescribed from biomechanical assessment vs non-prescribed shoes</td>
<td>n=217 (122/95) 20-60 (37.8) NR NR</td>
<td>Sport Shoe Selection (SSS) system is described, but variables not reported</td>
<td>Self-reported survey</td>
</tr>
<tr>
<td>Theisen, D. et al. 2014 Luxembourg</td>
<td>RCT (5-month) standard, cushioned shoes with different midsole hardness</td>
<td>n=247 (136/111) 18+ (41.8) 23.6 Recreational</td>
<td>Shoe type (standard cushioned) Heel-toe drop Midsole hardness Cushioning</td>
<td>Manufacturer definition Type by measurements Not reported Asker C durometer Impact test</td>
</tr>
<tr>
<td>Withnall, R. et al. 2006 United Kingdom</td>
<td>RCT (7-month) Insole materials (Saran, Sorbothane, Poron)</td>
<td>n=1205 (937/268) 16-35 (19.6) 22.9 Royal Air Force basic training</td>
<td>Innersole thickness Materials (insole) Cost</td>
<td>Not reported Manufacturer definition Not reported</td>
</tr>
</tbody>
</table>
3.3.3 Quality Assessment

Agreement between the two reviewers was excellent (Kappa=0.86) when assessing the methodological quality of the included studies. Twelve (46%) of the included studies had high methodological quality (Table 3.2): eight were RCT [43, 47, 48, 63, 66, 139, 154, 156], three were prospective[74, 138, 152] and one was retrospective [155] in design. External validity and participant selection were the most common sources of bias among the studies with low methodological quality [45, 50, 64, 65, 75, 78, 136, 151, 153, 157-159].
Table 3.2: Downs and Black Quality Assessment

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Design</th>
<th>Reporting</th>
<th>External Validity</th>
<th>Internal Validity</th>
<th>Selection Bias</th>
<th>Power</th>
<th>Total</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Altman, A.R. et al. 2016</td>
<td>P</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
<td>1 1 X</td>
<td>X X 0 X 1</td>
<td>1 1 X X 1</td>
<td>1 1</td>
<td>17</td>
</tr>
<tr>
<td>Caution, D.J. et al. 2012</td>
<td>CS</td>
<td>1 1 1 X</td>
<td>1 1 0</td>
<td>0 0 1</td>
<td>X X X X X</td>
<td>1 X X X 0</td>
<td>X 0</td>
<td>7</td>
</tr>
<tr>
<td>Cohler, M.H et al. 2015</td>
<td>R</td>
<td>1 1 X X X</td>
<td>1 0 0</td>
<td>0 1 X</td>
<td>X X X X 0</td>
<td>1 1 X X X</td>
<td>1 0</td>
<td>8</td>
</tr>
<tr>
<td>Di Caprio, F. et al. 2010</td>
<td>P</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
<td>1 1 X</td>
<td>X X X 0 X</td>
<td>1 1 X X X</td>
<td>1</td>
<td>12</td>
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<tr>
<td>Dubois, B. et al. 2015</td>
<td>RCT</td>
<td>1 1 1 1 2</td>
<td>1 1 1</td>
<td>0 1 1</td>
<td>1 1 0 X</td>
<td>1 1</td>
<td>0 1 1 1 1</td>
<td>1</td>
</tr>
<tr>
<td>Fuller, J.T. et al. 2017</td>
<td>RCT</td>
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<td>1 1</td>
<td>0 0 0</td>
<td>0 0 1 1</td>
<td>1 0 1 1 1</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Gardner, L.I. et al. 1988</td>
<td>RCT</td>
<td>1 1 0 1</td>
<td>1 1</td>
<td>1 0</td>
<td>0 1</td>
<td>0 X</td>
<td>1 1</td>
<td>0 1</td>
</tr>
<tr>
<td>Giuliani, J. 2011</td>
<td>CS</td>
<td>1 1 1 X</td>
<td>1 1 0</td>
<td>0 0 1</td>
<td>X X X X X</td>
<td>1 X X X 0</td>
<td>X 0</td>
<td>7</td>
</tr>
<tr>
<td>Goss, D.L. et al. 2012</td>
<td>R</td>
<td>1 1 1 X</td>
<td>1 1 0</td>
<td>1</td>
<td>1 1 0</td>
<td>X X 0 X</td>
<td>1 0</td>
<td>1 0 0 0</td>
</tr>
<tr>
<td>Grier, T.L. et al. 2016</td>
<td>P</td>
<td>1 1 1 X</td>
<td>0 1 1</td>
<td>1</td>
<td>0 1</td>
<td>X X X X</td>
<td>1 1</td>
<td>1</td>
</tr>
<tr>
<td>Knapik, J.J. et al. 2009</td>
<td>RCT</td>
<td>1 1 1 1</td>
<td>0</td>
<td>1 1</td>
<td>0 1</td>
<td>0 1 1</td>
<td>1 1</td>
<td>1 0</td>
</tr>
<tr>
<td>Knapik, J.J. et al. 2010a</td>
<td>RCT</td>
<td>1 1 1 1</td>
<td>0</td>
<td>1 1</td>
<td>0 0</td>
<td>0 1</td>
<td>1 1</td>
<td>1</td>
</tr>
<tr>
<td>Knapik, J.J. et al. 2010b</td>
<td>RCT</td>
<td>1 1 1 1</td>
<td>2</td>
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<td>1</td>
<td>0 1</td>
<td>0 1 1</td>
<td>1</td>
</tr>
<tr>
<td>Malisouxs, L. et al. 2016a</td>
<td>RCT</td>
<td>1 1 1 1</td>
<td>2</td>
<td>1 1</td>
<td>1</td>
<td>0 0</td>
<td>X</td>
<td>1 1</td>
</tr>
<tr>
<td>Malisouxs, L. et al. 2015</td>
<td>P</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
<td>1</td>
<td>1 0</td>
<td>X</td>
<td>0 1</td>
<td>0 1</td>
</tr>
<tr>
<td>Malisouxs, L. et al. 2016b</td>
<td>RCT</td>
<td>1 1 1 1</td>
<td>2</td>
<td>1 1</td>
<td>1</td>
<td>0 1</td>
<td>1 1</td>
<td>1</td>
</tr>
<tr>
<td>Nielsen, R.O. et al. 2014</td>
<td>P</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
<td>1</td>
<td>0 0</td>
<td>1</td>
<td>0 1 1</td>
<td>1</td>
</tr>
<tr>
<td>Osterman, K. et al. 2016</td>
<td>R</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
<td>1</td>
<td>0 0</td>
<td>0</td>
<td>X X</td>
<td>0 1</td>
</tr>
<tr>
<td>Ryan, M.B. et al. 2011</td>
<td>RCT</td>
<td>1 1 0 1</td>
<td>1 1</td>
<td>0 0</td>
<td>0 1</td>
<td>1 1 1</td>
<td>1 0</td>
<td>0 1 0</td>
</tr>
<tr>
<td>Ryan, M.B. et al. 2014</td>
<td>RCT</td>
<td>1 1 1 1 2</td>
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<td>0 1 0</td>
<td>0 0 1</td>
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<td>1 1 0</td>
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<tr>
<td>Salzler, M.J. et al. 2012</td>
<td>R</td>
<td>1 1 1 X</td>
<td>0 1 0</td>
<td>0</td>
<td>0 1</td>
<td>X X X X X</td>
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<td>1 0</td>
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<tr>
<td>Salzler, M.J. et al. 2016</td>
<td>P</td>
<td>1 1 1 X</td>
<td>2 1 1</td>
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<td>0 0</td>
<td>X</td>
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<td>1 1 1 X</td>
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<td>0</td>
<td>1 1</td>
<td>X X</td>
<td>0 1</td>
</tr>
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<td>Theisen, D. et al. 2013</td>
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<td>1 1</td>
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<td>0 0</td>
<td>1</td>
<td>1 0 x</td>
<td>1 1</td>
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<td>1 1 1</td>
<td>NA</td>
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<td>X 0</td>
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<tr>
<td>Withnall, R. et al. 2006</td>
<td>RCT</td>
<td>1 1 1 1 0</td>
<td>1 1 1</td>
<td>1 1 1</td>
<td>0 0 0 1</td>
<td>1 1 0</td>
<td>0 1 1</td>
<td>1 7</td>
</tr>
</tbody>
</table>
3.3.4 Footwear Characteristics

Twenty-nine different footwear characteristics were identified among the included studies. These were grouped into four categories: nomenclature, measurements, qualitative features and subjective features. Four studies [75, 152, 155, 160] reported only one footwear characteristic, six studies reported two [47, 74, 78, 136, 153, 157] and three [45, 63-65, 139, 156] characteristics, five studies [50, 138, 154, 158, 159] reported four characteristics, three studies [43, 48, 151] reported five characteristics and two studies [66, 76] reported six characteristics (Table 3.3).

Table 3.3: Footwear characteristics and assessment tools reported

<table>
<thead>
<tr>
<th>Category</th>
<th>Characteristic (reference)</th>
<th>Assessment tools (reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nomenclature</td>
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<td></td>
<td>Neutral [48, 50]</td>
<td>Custom Definition [74, 76, 78, 159]</td>
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<td>Cushioned [63-65, 76]</td>
<td>PCECH definition [50, 159]</td>
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<td>Motion-control [50, 63-66, 76]</td>
<td>Self-report [74, 136, 157]</td>
</tr>
<tr>
<td></td>
<td>Minimalist [43, 45, 47, 74, 76, 78, 136, 157, 159, 160]</td>
<td>Runner’s world magazine [65]</td>
</tr>
<tr>
<td></td>
<td>Modern-day [74]</td>
<td>Type by measurements [139, 153]</td>
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<td></td>
<td>Neutral plus [159]</td>
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<td>Conventional [43]</td>
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<tr>
<td></td>
<td>Barefoot-simulating [75]</td>
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<td>Standard [66]</td>
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<tr>
<td></td>
<td>Standard cushioned [139]</td>
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<tr>
<td></td>
<td>Partial minimalist [48]</td>
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</tr>
<tr>
<td>Category</td>
<td>Characteristic (reference)</td>
<td>Assessment tools (reference)</td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Measurements</td>
<td><strong>Heel-toe drop</strong> [43, 66, 138, 139, 154, 159]</td>
<td><em>None reported</em> [43, 48, 66, 138, 139, 153, 154, 156]</td>
</tr>
<tr>
<td></td>
<td><strong>Midsole thickness</strong> [43, 48, 138, 154]</td>
<td><em>Asker-C durometer</em> [66, 139]</td>
</tr>
<tr>
<td></td>
<td><strong>Minimalist index</strong> [22]</td>
<td><em>Impact Test</em> [139]</td>
</tr>
<tr>
<td></td>
<td><strong>Innersole thickness</strong> [156, 158]</td>
<td><em>Minimalist Index Tool</em> [43]</td>
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<td></td>
<td><strong>Mass</strong> [43, 48, 153]</td>
<td><em>Self-reported</em> [76, 151, 158]</td>
</tr>
<tr>
<td></td>
<td><strong>Midsole hardness</strong> [66, 139, 154]</td>
<td><em>Visual inspection</em> [50, 66, 151, 159]</td>
</tr>
<tr>
<td></td>
<td><strong>Stability elements</strong> [50, 66, 151]</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Shoe age</strong> [76, 151, 158]</td>
<td></td>
</tr>
<tr>
<td>Qualitative</td>
<td><strong>Shoe construction</strong> [151]</td>
<td><em>None reported</em> [156]</td>
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<tr>
<td>Features</td>
<td><strong>Midsole material</strong> [66, 138, 151]</td>
<td><em>Visual inspection</em> [138, 151, 158]</td>
</tr>
<tr>
<td></td>
<td><strong>Innersole material</strong> [156, 158]</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Outer-sole wear patterns</strong> [151]</td>
<td></td>
</tr>
<tr>
<td>Subjective</td>
<td><strong>Comfort</strong> [45]</td>
<td><em>None reported</em> [156]</td>
</tr>
<tr>
<td>Features</td>
<td><strong>Shoe selection</strong> [155]</td>
<td><em>Self-reported (participant)</em> [45]</td>
</tr>
<tr>
<td></td>
<td><strong>Cost</strong> [156, 158]</td>
<td><em>Self-reported (survey)</em> [152, 155, 158]</td>
</tr>
<tr>
<td></td>
<td><strong>Multiple shoe use</strong> [152]</td>
<td></td>
</tr>
</tbody>
</table>

3.3.4.1 Nomenclature

All studies, except five [151, 152, 155, 156, 158], reported at least one type of footwear included in the study. The following terms were most commonly used to describe running style footwear: ‘traditional’, ‘neutral’, ‘stability’, ‘cushioned’, ‘motion-control’ and

3.3.4.2 Footwear Measurements

Thirteen studies reported specific measurements of the study footwear. These measurements include: heel-toe drop, midsole thickness, minimalist index, innersole thickness, mass, midsole hardness, stability elements, and shoe age.

3.3.4.3 Qualitative Features

Five studies reported features regarding the objective quality of the study footwear. These characteristics include: shoe construction/integrity, midsole material, innersole material, and outer-sole wear patterns.

3.3.4.4 Subjective Features

Subjective features were identified in five studies, in which the study footwear was assessed with respect to the runner. These features include: shoe comfort, a system for shoe selection based on biomechanical lower limb alignment, cost, and the use of multiple shoes.
3.3.5 Footwear Assessment Methods

Fifteen methods of assessing the 29 footwear characteristics were reported in the included studies (Table 3.4). Although all 25 publications in this review assessed footwear characteristics as independent variables, only five studies (19%) used assessment tools which had been previously described [43, 50, 139, 154, 159]. The minimalist index tool [22] was used to describe the degree of minimalism, heel-toe drop, stack height, mass and motion control technology in one study [43]. A durometer was used to assess the midsole hardness in two studies [66, 139]. A standardised definition of traditional footwear [131] was noted in two studies [50, 159]. One study utilised a standard impact test [161] to determine the amount of midsole compression [139]. No studies in this review presented the reliability or validity for the assessor’s measurements of footwear characteristics.

3.3.5.1 Nomenclature

Seven methods were used to determine footwear nomenclature of the 13 different footwear types reported. Footwear type was determined by using the brand and model, custom definitions, the manufacturers definition, the Pronation Control Elevated Cushioned Heel (PCECH) shoes definition [131], self-reported data, Runners-World magazine, and specific footwear measurements.

3.3.5.2 Brand and model

Fifty footwear brand and models (Appendix 3) were reported across eleven studies [43, 45, 47, 48, 50, 63-65, 75, 138, 154]. Three studies [43, 45, 47] identified seven brands as
minimalist. Three studies [63-65] identified nine brands as cushioned. Four studies [50, 63-65] identified six brands as motion control. Three studies [48, 50, 138] identified two brands and neutral. Four studies [50, 63-65] identified ten brands as stability. One study [47] identified eight brands as traditional. Asics Gel Cumulus was reported as a cushion [65] and conventional shoe [43]. Nike Pegasus was reported as a neutral [48, 50] and cushion [65] shoe. Nike Structure Triax was reported as a stability shoe by two studies [48, 65]. One study [76], reported that brand and model was collected, however, this information was not reported in the manuscript.

3.3.5.3 Custom definitions

Four studies expressed specific criteria derived from non-standardised sources to describe footwear as minimalist [74, 78, 159], modern day shoes [74] and traditional [74, 76, 78].

3.3.5.4 Minimalist Index

The minimalist index [22] was used by Fuller et al. [43] to verify the types of shoes (minimalist and conventional) by indicating the minimalist index as 72% and 12%, respectively. The Minimalist Index is a valid and reliable tool [162], however, the psychometric properties of the tool nor the assessors were provided.

3.3.5.5 Manufacturer definition

Thirteen studies reported footwear type based on the manufacturer discretion. Footwear was reported as: minimalist [45, 47, 48, 76], traditional [47, 76], barefoot-simulating [75], motion-
control [50, 63-66], stability [50, 63-65], cushioned [63-65], standard [66], standard-cushioned [139, 154], and neutral [50, 138].

3.3.5.6 Pronation control elevated cushioned heel definition

Two studies reported footwear as traditional [159], neutral, motion control or stability [50], using the previously described PCECH definition [131].

3.3.5.7 Self-reported

Four studies used self-reported footwear type from the study participants. Footwear was reported as modern-day shoes [74], minimalist [74, 136, 157, 160], and traditional [136].

3.3.5.8 Runners-world

Two studies used Runners-World Magazine and website as sources of assessing and cross-verifying footwear type as either: standard, cushioned or motion control [65, 76].

3.3.5.9 Type by measurements

Three studies reported footwear type by measuring the footwear mass [43, 153], heel-height and heel-toe-drop [43], and midsole hardness [139]. Di Caprio et al. [153] described the study footwear as superlight (<250 g), light (250-300 g), or shock-absorbing (>300 g). Fuller et al. [43] described conventional shoes as: 333 g (± 25 g); 32 mm heel-height; 9 mm heel-toe drop and minimalist shoes as: 138 g (± 9 g); 22 mm heel-height; 5 mm heel-toe drop. Theisen et al.
[139] described two versions of the same standard-cushioned shoe as ‘hard’ (64.47 ± 2.22 Asker C arbitrary units) or ‘soft’ (57.02 ± 2.96 Asker-C arbitrary units) [139].

### 3.3.6 Footwear Measurements

Five different methods were reported by seven studies for the measurements of specific footwear characteristics. Measurements were assessed using an Asker-C durometer, the Minimalist Index [22] an impact test [161], visual inspection and self-reported data. Nine studies did not report any method for the measurement of heel-toe drop [43, 66, 138, 139, 154, 159], mass [43, 48, 153], midsole thickness [43, 48, 138, 154], and innersole thickness [156, 158].

#### 3.3.6.1 Asker-C durometer

An Asker-C durometer was used to measure the midsole hardness of standard and motion-control shoes [66] and standard-cushioned shoes [139].

#### 3.3.6.2 Impact test

One study used a standard impact test (ASTM standard F1976-06) to indicate the cushioning properties of the study footwear [139]. This method was previously reported as being valid and is commonly used in the manufacturer testing of footwear properties [161]. Mean values (and standard deviation) were reported for the hard shoes: 58.7 (±2.8) kN/m and soft shoes 51.1 ±4.0 kN/m.
3.3.6.3 Minimalist index

The minimalist index is a valid and reliable footwear assessment tool that determines how minimal a shoe is by categorizing six subscales: mass, stack height, heel-toe drop, stability and motion control technologies and flexibility (longitudinal and torsional). The higher the shoe scores on the scale, the more minimal its properties. One study in this review [43] used the minimalist index [162] and rated the minimalist shoes used in the study as 72% minimal versus the conventional shoes which were rated as 12% minimal.

3.3.6.4 Self-reported

Two studies used self-reported data from the study participants to determine the shoe age and usage [151, 158].

3.3.6.5 Visual inspection

Three studies [50, 66, 151] relied on a visual inspection of footwear characteristics to verify the presence of stability elements such as: heel-counter, thermoplastic midfoot shank, posterolateral crash pad, lateral sole flare, and dual-density EVA midsole.

3.3.7 Qualitative features

Visual inspection was used to determine the shoe construction and wear patterns [151]. No study reported methods for determining innersole material [156, 158] and midsole material [138, 151, 154]
3.3.8 Subjective features

Four studies used self-reported data to determine: the shoe cost [156, 158], use of multiple shoes [152], and shoes selected by the Shoe Selection System (SSS) [155]. One study did not report the method of determining footwear comfort [45].
### Table 3.4: Assessment tools used per footwear characteristic in studies of RRI

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Injuries Reported (n=3526)</th>
<th>Assessment tools</th>
<th>Psychometric Properties (Reference of original source)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nomenclature</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cushioned</td>
<td>302*</td>
<td>Brand/Model [63-65, 76]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition [76]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition [63-65, 76]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Runner’s World Magazine/website [65, 76]</td>
<td>N/A</td>
</tr>
<tr>
<td>Minimalist</td>
<td>418</td>
<td>Brand/Model [43, 45, 47, 48, 75, 138]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition [74, 76, 78, 159]</td>
<td>Excellent within and between rater reliability (ICC &gt; 0.80) [22]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimalist Index [43]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition [43, 45, 47, 48, 75, 76, 138]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Self-Report (participant) [136, 157] [160]</td>
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</tr>
<tr>
<td>Motion Control</td>
<td>339*</td>
<td>Brand/Model [50, 63-65, 74]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition [76]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition [50, 63-66, 76]</td>
<td>No psychometric properties reported [131]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PCECH Definition: [50]</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Runner’s World Magazine/website: [65, 76]</td>
<td>N/A</td>
</tr>
<tr>
<td>Neutral</td>
<td>327</td>
<td>Brand/Model [48, 50]</td>
<td>N/A</td>
</tr>
<tr>
<td>Stability</td>
<td>135*</td>
<td>Brand/model: [63, 64 Ryan, 2011 #19, 65]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition: [76]</td>
<td>N/A</td>
</tr>
<tr>
<td>Characteristic</td>
<td>Injuries Reported (n=3526)</td>
<td>Assessment tools</td>
<td>Psychometric Properties (Reference of original source)</td>
</tr>
<tr>
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<td>--------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition: [50, 63-65, 76]</td>
<td>No psychometric properties reported [131]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PCECH Definition: [50]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Runner’s World Website: [76]</td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td>665</td>
<td>Brand/Model: [45, 47, 138]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition: [76]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition: [45, 47, 76, 138]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Runner’s World Website: [76]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Self-Report (Participants): [157]</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>573</td>
<td>Brand/Model: [43, 154]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Custom Definition: [74]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minimalist Index Tool: [43]</td>
<td>Excellent within and between rater reliability (ICC &gt; 0.80) [22]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturer Definition: [43, 48, 66, 139, 154]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Type by Measurements: [139, 153]</td>
<td></td>
</tr>
<tr>
<td>Measurements</td>
<td></td>
<td>None reported: [43, 66, 138, 139, 154]</td>
<td>N/A</td>
</tr>
<tr>
<td>Heel-toe drop</td>
<td>667</td>
<td>Visual Inspection: [159]</td>
<td></td>
</tr>
<tr>
<td>Midsole Thickness</td>
<td>696</td>
<td>None reported: [43, 48, 138, 154]</td>
<td>N/A</td>
</tr>
<tr>
<td>Innersole Thickness</td>
<td>221</td>
<td>None reported: [156]</td>
<td>N/A</td>
</tr>
<tr>
<td>Mass</td>
<td>353</td>
<td>None reported: [43, 48, 153]</td>
<td>N/A</td>
</tr>
<tr>
<td>Midsole Hardness/Cushion</td>
<td>247</td>
<td>Asker-C/Shore A Durometer: [66, 139]</td>
<td>Validity questionable [163]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Impact Test: [139]</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>None reported: [154]</td>
<td></td>
</tr>
<tr>
<td>Characteristic</td>
<td>Injuries Reported (n=3526)</td>
<td>Assessment tools</td>
<td>Psychometric Properties (Reference of original source)</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------</td>
<td>-----------------------------------------</td>
<td>-------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No psychometric properties reported [161]</td>
</tr>
<tr>
<td>Minimalist Index</td>
<td>61</td>
<td>Minimalist Index Tool: [43]</td>
<td>Excellent within and between rater reliability (ICC &gt; 0.80)[22]</td>
</tr>
<tr>
<td>Stability Elements</td>
<td>288</td>
<td>Self-reported: [151]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Visual inspection: [50, 66, 151]</td>
<td>N/A</td>
</tr>
<tr>
<td>Shoe age/usage</td>
<td>1371</td>
<td>Visual Inspection: [76, 151, 158]</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Qualitative Features**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Injuries Reported</th>
<th>Assessment tools</th>
<th>Psychometric Properties (Reference of original source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Construction/Integrity</td>
<td>1</td>
<td>Visual Inspection: [151]</td>
<td>N/A</td>
</tr>
<tr>
<td>Innersole Material</td>
<td>259</td>
<td>Visual Inspection: [156, 158]</td>
<td>N/A</td>
</tr>
<tr>
<td>Midsole Material</td>
<td>306</td>
<td>Visual Inspection: [138, 151]</td>
<td>N/A</td>
</tr>
<tr>
<td>Wear Patterns</td>
<td>1</td>
<td>Visual Inspection: [151]</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Subjective Features**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Injuries Reported</th>
<th>Assessment tools</th>
<th>Psychometric Properties (Reference of original source)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comfort</td>
<td>12</td>
<td>Self-reported:[45]</td>
<td>N/A</td>
</tr>
<tr>
<td>Shoe Prescription</td>
<td>72</td>
<td>Sport shoe selection system: [155]</td>
<td>No assessment found [164]</td>
</tr>
<tr>
<td>Cost</td>
<td>259</td>
<td>None reported: [156]</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Survey: [158]</td>
<td>N/A</td>
</tr>
<tr>
<td>Multiple shoes</td>
<td>87</td>
<td>Survey: [152]</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*excludes absolute number of injuries from military studies*
3.4 Discussion

The purpose of this Chapter was to evaluate the methods used to assess footwear characteristics among studies on RRI. We identified and categorised 15 different methods for assessing 29 footwear characteristics into four categories: nomenclature, footwear measurements, qualitative features and subjective features.

3.4.1 Quality assessment

Only 12 of the included studies presented high methodological quality. A lack of clear reporting of participant recruitment methods reduced the external validity and generalisability of results from these studies. Studies had a low bias of internal validity apart from participant and assessor blinding. However, blinding in footwear studies is often difficult, and may not be relevant to the study aims.

3.4.2 Nomenclature

External validity would be improved if terms such as ‘motion-control’ or ‘neutral’ were used consistently and included defined parameters. It is contended here that a taxonomy for all shoe types, with clear definitions, is a priority before establishing relationships between footwear and injury. This review found 13 different terms used to describe two general types of footwear (minimalist and traditional). Although footwear is often considered dichotomous [49] it is important to use consistent terms when describing the various types of footwear. As differences between motion-control and neutral footwear are evident, it is less evident what differentiates motion-control from stability footwear. The term ‘traditional’ lacks clear criteria
and is more of an umbrella term that encompasses many styles of non-minimalist running shoes. Therefore, it is incorrect to categorize shoes as ‘traditional’, when assessing a specific style of cushioned footwear.

Although a consensus definition and rating scale is available for minimalist footwear [22] several limitations affect its use for identifying footwear taxonomy. The minimalist definition lacks measurable criteria to describe minimalist footwear and should only be used in conjunction with the minimalist index. The minimalist index is useful for evaluating injury risk and making recommendations on safe transitions between footwear with varying levels of minimalism. However, this tool does not distinguish between types of footwear and uses a percentage rating scale, indicating potentially 100 different stages of footwear. Rixe et al. (2012) [49] has suggested that minimalist footwear should be less than 8oz (226 g) and have a heel-toe drop less than 5mm. However, this is not a validated definition of minimalist footwear, but are the suggested maximum values of minimalist footwear that will allow runners to obtain the biomechanical markers associated with barefoot running [49]. This may be a starting point for using the rating scale to distinguish between levels of minimalist footwear.

The use of specific measurements to classify footwear type are an important step to establishing taxonomy criteria. Measuring properties such as the heel-toe drop or midsole hardness improves the external validity and identifies discrepancies between manufacturers and studies. For example, two studies [66, 139] included in this review used custom footwear developed from renowned manufacturers and included specific measurements to assess the type of shoes. The only reported differences between the standard and motion-control shoes was the 15% hardness difference between the medial and lateral midsoles of the motion-control shoes [66].
3.4.3 Footwear Measurements

Some limitations are present for the objective measurements (stack height and heel-toe drop) of the Minimalist Index Tool, which Fuller et al. [43] used to measure the footwear characteristics included in their study. According to the instructional guide presented with the Minimalist Index Tool [22], proper measurement with digital callipers indicates the footwear to be cut longitudinally (Figure 4) to access the central point of the rearfoot and the forefoot, thus requiring a subset of footwear to be tested. Additionally, only the thickness of the centre of the rearfoot and forefoot are measured. This excludes the mediolateral asymmetry of midsole thickness which may be a result of design and or degradation and could influence biomechanics and/or injury.

Medial and lateral shoe wedges and orthoses are often used to alter biomechanics in patients with knee osteoarthritis [61] and a wedge effect may be present in running style footwear, either by design or degradation. A method of assessing mediolateral asymmetry which does not require footwear subsets, has been previously described [165]. However, the reliability of the total asymmetry score has not be established in the literature.

Our findings suggest that the internal and external validity of footwear measurements is questionable. Only two studies indicated the devices used for assessing footwear measurements [66, 139]. Malisoux et al. (2016) [66] and Thiesen et al. (2013) [139] specified using an Asker-C durometer to measure midsole hardness. Malisoux et al. (2016) [66] acquired hardness measurements from the sagittal plane of the midsoles, cut at the meta-tarsal head. This was an appropriate method for the study as the dual-density midsole was placed in the forefoot of the custom prototype shoe used in the study. When assessing midsole hardness with the Asker-C durometer, an average of five [66] and three [139] trials were used on a
subset of 24 [66] and 116 [139] shoes. Neither study reported the assessor reliability of the hardness measurements.

Two important limitations are present with the method described by Malisoux et al. (2016) [66]. First, a subset (n=12 per model) of shoes were tested because the models were cut and therefore were not usable by participants. Second, many commercially available motion-control shoes are designed with the dual-density midsole features at the rearfoot [166, 167] limiting the generalisability of results to studies without custom footwear or prototypes.

Alternative methods of assessing midsole hardness may be required for use in studies without subsets and/or with commercially available footwear. Sole et al. (2012) assessed the mediolateral differences of midsole hardness using the mode of durometer readings from the outer edge of the rearfoot and forefoot [124, 128, 165]. A recent study found a durometer to be an objective and accurate measurement of midsole hardness [168]. Additionally, the midsole hardness significantly increased by 17% over 480 km and the runners were unable to perceive the changes after 640 km [168], indicating that midsole hardness measurements are valuable to clinicians and researchers evaluating the effects of footwear characteristics on RRI.

The validity of midsole properties measurement for indicating injury has been questioned. Shorten and Mientjes (2011) [163] argue that durometer measurements yield indentation hardness rather than impact attenuation and reporting cushioning properties based on indentation hardness is not appropriate. Theisen et al. (2013) [139] assessed the cushioning properties of the heel region of a subset shoes (n=24) using a standard impact test. However, the standard impact test [161] has limited predictive value in determining the shock attenuation of footwear [169] and is an invasive process that may inhibit the use of footwear by study participants. Valid and reliable methods of assessing footwear midsole properties are needed to evaluate the relationships between footwear characteristics and RRI.
This review suggests heel-toe drop is the most reported footwear measurement. This measure is commonly used for descriptive purposes only. Shoes categorized as minimalist had heel-toe drops ranging from 5 mm to 6 mm, [43, 159] and shoes with a heel-toe drop ranging from 0 mm to 12 mm were reported as stability, [159], conventional, [43] motion control, [66] standard, [66] standard cushioned, [139, 154], and neutral [138]. Several important considerations are required when assessing heel-toe drop. If heel-toe drop is to be used as defining criteria between different types of footwear, the inter- and intra-rater reliability of the measurements must be reported in addition to the standard error of measurements. Previous studies used a ruler to measure the heel-toe drop [23, 133] while others have used digital callipers [162, 165, 170].

Various measurement locations for heel-toe drop have also been reported. Barton et al. [23] used an average of mediolateral measurements of the mid- and outer-soles at the rearfoot (heel-sole interface) and forefoot (metatarsal heads). Esculier et al. [22] suggest measuring heel-toe drop from the thickest point of the centre of the rearfoot and forefoot (including the inner, mid and outer-soles). The images depicting the methodology by Esculier [22] (Figure 4) show footwear that have been cut to allow the calliper placement at the centre of the shoe. This induces similar complications of using subsets as described earlier regarding midsole hardness.

The role of footwear measurements such as hardness, cushioning, and thickness on injury needs further assessment in the literature.
3.4.4 Qualitative Features

Innersole material [156, 158] and overall shoe construction [151] were qualitative features that were assessed in relation to RRI. Midsole material and wear patterns were described but not considered as risk factors. Wilk et al. (2000) [151] proposed that the injured patient may have developed plantar fasciitis due to defective shoe construction, rather than shoe design or biomechanical abnormalities. When assessing footwear integrity, these authors found a manufacturer error in the shoe that corresponded with the patient’s injured side. The improper adherence of the upper to the midsole may have caused the patient to adopt compensatory mechanics or restrict normal gait variability, causing injury.

The clinical report by Wilk et al. (2002) [151] expresses that manufacturer defects are present in running shoes and may be indicative of injury. Currently, no known tools are available to objectively assess the angle of the shoe upper in relation to the midsole. Tools
such as the Total Asymmetry Score [165] may assist in identifying other errors in design or degradation of the inner, mid and outer-soles. It could be expected that this clinical interpretation of defective footwear would stimulate scientific research regarding the integrity of footwear construction characteristics. However, our review found no other studies (clinical or scientific) that evaluated footwear characteristics in this manner.

A previously validated method of assessing footwear characteristics [23], including shoe fixation, wear patterns, and materials may provide sufficient items for describing footwear characteristics. However, more quantitative measures are needed to improve the significance of the individual assessments within the tool. When reviewing the manufacturing processes of many major footwear companies, materials and assembly use complex and varied procedures which are often outsourced overseas [172]. Additionally, the procedures differ depending on manufacturing and assembly location [173]. Because of the varied processes of manufacturing athletic footwear, it is important for research reports to verify footwear materials and technologies before identifying causal relationships to injury. Establishing a range of optimal footwear characteristics for a variety of patient populations may provide clinical guidance and could be utilized in research settings [23].

### 3.4.5 Subjective Features

Salzler et al. (2012) [45] indicated participants selected comfortable footwear before transitioning to minimalist shoes. However, despite the availability of a valid and reliable method of assessing footwear comfort, these data were not reported in the study by Salzler et al. (2012). Previous studies have found footwear with comfortable shoe inserts to reduce back, leg and foot pain [174] and reduce the incidence of stress fractures [175]. Additionally,
comfortable footwear increases performance [176], and reduces kinetic variability during running [177].

3.4.6 Strengths and Limitations

This Chapter included 26 studies with various designs. To our knowledge this is the first review to systematically evaluate how and what footwear characteristics are assessed in studies focusing on RRI. However, injury outcomes could not be collated due to the methodological shortcomings of assessing and reporting footwear may affect the injury data at the study level.

A modified version of the Downs and Black quality assessment tool was used to assess the quality of included studies. The Downs and Black tool is which is intended to assess public health studies of randomised and non-randomised design [146]. Many reviews, including this one, have modified the Downs and Black checklist to fit a topic other than the intended [61, 77, 122, 178-180]. However, the modified tool can no longer be considered valid and reliable under a modified version, unless the properties of the modified version are tested for validity and reliability [181]. Therefore, caution is warranted when interpreting the quality of the included studies in this review. While many quality assessment tools are available [182], none are available which are intended to assess footwear studies. The external validity of this study is limited as this review only included studies which evaluated footwear intended for running and where injury or pain was an outcome in runners.
3.4.7 Future implications

This review reveals gaps in the literature where precise and clear reporting of footwear could improve the internal and external validity of studies and provide high quality evidence of causal or preventative relationships to RRI.

Some studies in this review pre-date the definition and rating scale presented by Esculier et al. [22]. Future studies are urged to recognise that failing to use relevant footwear assessments and reporting criteria, limits the methodological rigour and threatens external validity. As different footwear types are often compared [49], a Delphi study may be relevant to develop a consistent footwear taxonomy. This will improve the classification and description of multiple footwear types [131] and allow for monitoring changes in footwear over time. We expect future studies to use established methods and tools for assessing footwear measurements such as heel-toe drop [162], midsole and innersole thickness [165]. Furthermore, valid and reliable methods to assess other footwear characteristics may be warranted. Other factors to consider in footwear assessments include fit, last shape, and midsole wear patterns [23, 133, 165, 166, 183-186].

Studies assessing footwear characteristics over time are needed to demonstrate the changes that inner, mid, and outer-sole materials undergo throughout use and time. Poorly described shoes in current studies clouds the relationship that may exist between footwear and RRI. The use of footwear assessment tools is needed to clarify these relationships. Future high-quality studies are required to address the structural differences and changes of footwear and their relationship between biomechanics, performance and running-related injuries.
3.5 Conclusion

Studies assessed footwear characteristics that can be divided into four categories: Nomenclature, measurements, qualitative features and subjective features. Appropriate footwear assessment tools are needed to determine the relationships between footwear characteristics and RRI. Clinicians and researchers can enhance footwear reporting by using established valid and reliable assessment tools, or developing tools where assessments are lacking.

3.6 In the next Chapter

The next Chapter builds on the data presented in the current chapter and evaluates the association between footwear characteristics and RRI.
4 CHAPTER 4: EXAMINING THE ASSOCIATION BETWEEN FOOTWEAR CHARACTERISTICS AND RRI

4.1 Chapter overview

This Chapter includes a secondary analysis of the articles identified in Chapter 3. Initially, this Chapter was going to provide a meta-analysis on the effectiveness of footwear interventions in studies of RRI. However, due to the methodological inconsistencies presented in Chapter 3, it became evident that such analyses could not be conducted. Therefore, an alternative aim was developed: to examine the association between footwear characteristics and RRI. This required the use of a non-systematic review approach called evidence mapping [187]. To prevent duplicating material, the eligibility criteria, electronic search (including the flowchart in Figure 3), and quality assessment is described only in sections 3.2.2 and 3.2.4.

4.2 Background (why analysis is needed in the context of this thesis)

It is generally understood that injury is an emergent property of the complex interactions of multiple related and non-related events [81, 83, 91, 103] and that one-to-one relationships between injury and specific risk factors cannot be determined [83]. Despite this general understanding, there are multiple studies that attempt to establish linear cause-effect relationships between footwear characteristics and RRI (Chapter 3). Indeed, as presented in Chapter 3, there is a lack of consistency between studies when describing footwear nomenclature, measurements, qualitative features and subjective features. Ultimately, this heterogeneity causes complications when combining evidence.
Yet, compiling evidence about association between risk factors and RRI is valuable information for key stakeholders (i.e. runners, clinicians). Several systematic reviews have identified footwear as a risk factor for RRI [16, 17, 19, 149, 188]. One review examined the risk of specific footwear types on RRI [77, 131] but a review has not been conducted on the association between specific footwear characteristics and RRI.

4.3 Methods

Compiling heterogeneous evidence requires the use of non-systematic review approaches [187]. For the purpose of this review, a customised pragmatic approach was used to analyse the level of evidence for the association between footwear characteristics and RRI. This method was deemed most appropriate to address the concerns with inconsistent methodological assessment of footwear [23, 189], and provide philosophical and practical implications to stakeholders within the footwear micro-system [81, 190, 191].

4.3.1 Data Extraction and analysis

The main data extraction regarding the characteristics of included studies and the quality assessment was completed in Chapter 3 and is contained in Table 3.1 and Table 3.2, respectively. However, for this secondary analysis, data was extracted on injury (anatomical location, specific injury type, and prevalence/incidence) as reported in each study.

Due to high heterogeneity between studies, effect sizes could not be determined. The level of evidence is based the guidelines of van Tulder et al. [192], which considers study design and strength of methodological quality (Table 3.2). Randomised controlled trials were considered the preferred study design, followed by cohort studies and case-control studies,
respectively. Ranking levels for the evidence was developed based on the following criteria:

1) Strong evidence was determined if consistent findings were reported for footwear characteristics in three or more RCTs and one cohort study with a high methodological quality;
2) Moderate evidence was determined when consistent findings were reported for footwear characteristics in two RCTs and one cohort study with high methodological quality; 3) Limited evidence is provided when positive injury outcomes were reported for footwear characteristics in one RCT with high methodological quality and one RCT with low methodological quality; 4) No evidence is provided when consistent findings were associated to footwear characteristics in only one RCT (high or low quality) or any cohort or case control studies (Error! Reference source not found.).

<table>
<thead>
<tr>
<th></th>
<th>RCTs</th>
<th>Cohort (prospective/retrospective)</th>
<th>Case controls/clinical trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong Evidence</td>
<td>3+ high methodological quality</td>
<td>1+ high methodological quality</td>
<td>Any</td>
</tr>
<tr>
<td>Moderate Evidence</td>
<td>2+ high methodological quality</td>
<td>1 high methodological quality</td>
<td>Any</td>
</tr>
<tr>
<td>Limited Evidence</td>
<td>1 high &amp; 1 low methodological quality</td>
<td>Any</td>
<td>Any</td>
</tr>
<tr>
<td>No Evidence</td>
<td>≤ 1 high methodological quality</td>
<td>Any</td>
<td>Any</td>
</tr>
</tbody>
</table>

4.4 Results

4.4.1 Injury Characteristics

A total of 3,526 injuries were reported from 10,321 participants. Absolute injury data from three military studies (7,232 participants) [63-65] was not available from the respective
manuscripts, and the authors were not contacted regarding this data. The highest reported injuries were by anatomical location (n=1,764) reported by 14 studies (Table 4.2). The knee was the most common location of injury (n=404, by 10 studies) and patellofemoral pain syndrome was the most reported musculoskeletal injury (n=84, by 3 studies).

Running-related pain or injury outcomes were presented as prevalence [45, 47, 50, 74, 75, 136, 153, 157-159] [160], incidence [48, 63-65, 138, 139, 152, 155], risk ratio [48, 63-65, 76, 138], hazard ratio [43, 66, 154], odds ratio [156], time to injury [78], or pain reduction [151].

4.4.2 Association between footwear characteristics and RRI

Eighteen footwear characteristics had a positive association to RRI. The level of evidence for the relationship of footwear characteristics to RRI is presented in (Table 4.3).
Table 4.2: Injury counts by population

<table>
<thead>
<tr>
<th></th>
<th>Novice</th>
<th>Recreational</th>
<th>Competitive</th>
<th>Endurance</th>
<th>Military*</th>
<th>Pop. Not specified</th>
<th>n (# of studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-specific Injury</td>
<td>4[138]</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>1112 [76, 158]</td>
<td>121 [48, 155]</td>
<td><strong>1237 (5)</strong></td>
</tr>
<tr>
<td>Total injuries</td>
<td><strong>136 (1)</strong></td>
<td><strong>553 (9)</strong></td>
<td><strong>1 (1)</strong></td>
<td><strong>27 (1)</strong></td>
<td><strong>1439 (3)</strong></td>
<td><strong>1370 (8)</strong></td>
<td><em><em>3526 (23</em>)</em>*</td>
</tr>
</tbody>
</table>

*no available data for 3 military studies [63-65]*
4.4.2.1 No Evidence

Among the footwear nomenclature category, no evidence was found for the effects of two types of footwear (stability and neutral) on RRI. Only one RCT with low methodological quality reported a positive association between footwear and injury [50]. Compared to neutral footwear, the use of stability shoes was associated with a protective factor for the experimental group (HR=0.88; 95%CI=0.70-1.10). One RCT with high methodological quality and one cohort study found positive injury associations between neutral shoes and RRI. Injury rates were reported as 3.56 injuries/1000 exposures [48] and 27% prevalence [138] among novice runners.

No evidence was found for the effects of any footwear measurements on RRI. Only one high-quality RCT reported injury rates with footwear that had a heel-toe drop 0mm (25% prevalence), 6mm (27% prevalence) and 10mm (22% prevalence) [154]. One high-quality RCT reported footwear with midsole hardness greater than 64 Asker-C units to be a protective factor from injury (HR: 0.92 95% CI = 0.57-1.48) [139]. One high-quality RCT reported an increased risk of injury with footwear scoring 72% on the minimalist index scale (HR: 1.64 95% CI = 0.63 – 4.27) [43].

No high-quality studies found associations between RRI and qualitative features or subjective features. Only low-quality studies observed the effects of shoe construction, innersole material, shoe selection, and multiple shoe use on RRI. However, the use of multiple shoes was statistically significant (HR=0.614, P=0.036) at reducing the risk of injury when compared to runners who only used a single pair of shoes during training [152]
4.4.2.2 Limited Evidence

Limited evidence was found for the relationship between traditional or motion control footwear and RRI. Three military studies observed similar injury rates of men and women basic training recruits [63-65] when wearing traditional style footwear. One of these studies found women to be 1.60 times more likely to sustain an injury when wearing stability style footwear.

4.4.2.3 Moderate Evidence

Moderate evidence was observed for the relationship between minimalist footwear and RRI. Prevalence was the most commonly reported injury statistic and ranged from 25% to 100% across all study designs. One RCT showed participants wearing minimalist footwear to have 1.64 times higher risk of injury when compared to conventional style shoes [43].

4.4.2.4 Strong Evidence

Strong evidence was not observed for the association of any footwear characteristic or measurement tool and RRI.
Table 4.3: Level of Evidence for injury associated to footwear characteristics

<table>
<thead>
<tr>
<th>Injury associated characteristic</th>
<th>Nomenclature</th>
<th>Injury Data</th>
<th>Randomised Control Trials</th>
<th>Observational cohort</th>
<th>Case studies</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimalist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Moderate Evidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>43% incidence [76]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hazard ratio 1.64 (95%CI=0.63-4.27)* [43]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>25% prevalence [47]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Traditional</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Limited Evidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hazard ratio men: 1.11 (95%CI=0.89-1.38)^ [63], 1.01 (95%CI=0.8-1.24)^ [64]; 1.01 (95%CI=0.88-1.16)^ [65]</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Hazard ratio women: 1.20 (95% CI= 0.90-1.60)^ [63], 1.07 (95%CI=0.91-1.25)^ [65]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>43% incidence^ [76]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>25% prevalence [47]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No evidence</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hazard ratio women: 0.88 (95%CI=0.70-1.10)^[64]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>40% incidence [76]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury associated characteristic</td>
<td>Injury Data</td>
<td>Level of evidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>---------------------------------</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Randomised Control Trials</td>
<td>Observational cohort</td>
<td>Case studies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motion Control</td>
<td>17.6% prevalence [66]</td>
<td></td>
<td>Limited Evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>44% incidence [76]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutral</td>
<td>3.56 injuries/ 1000 exposures [48]</td>
<td>27% prevalence [138]</td>
<td>No Evidence</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Measurements**

<table>
<thead>
<tr>
<th>Measurements</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>0mm heel-toe drop</td>
<td>25% prevalence [154]</td>
</tr>
<tr>
<td>6mm heel-toe drop</td>
<td>27% prevalence [154]</td>
</tr>
<tr>
<td>10mm heel-toe drop</td>
<td>22% prevalence [154]</td>
</tr>
<tr>
<td>Hard midsoles (64 ±2 Asker-C units)</td>
<td>Hazard ratio: 0.92 (95%CI=0.57-1.48)‡ [139]</td>
</tr>
<tr>
<td>72% minimalist index</td>
<td>Hazard ratio 1.64 (95%CI=0.63-4.27)* [43]</td>
</tr>
</tbody>
</table>

**Qualitative features**

<table>
<thead>
<tr>
<th>Qualitative features</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoe construction</td>
<td>100% prevalence [151]</td>
</tr>
<tr>
<td>Injury associated characteristic</td>
<td>Injury Data</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Insole material (poron)</td>
<td>19.8% prevalence [156]</td>
</tr>
<tr>
<td>Insole material (sorbothane)</td>
<td>17.3% prevalence [156]</td>
</tr>
<tr>
<td>Insole material (saran)</td>
<td>18.0% prevalence [156]</td>
</tr>
<tr>
<td>Insole material (mesh)</td>
<td>1.13% prevalence [158]</td>
</tr>
<tr>
<td>Insole material (polymer)</td>
<td>1.35% prevalence [158]</td>
</tr>
</tbody>
</table>

**Subjective features**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoe selection system</td>
<td>6.04 injuries/100 sessions [155]</td>
<td>No Evidence</td>
</tr>
<tr>
<td>Multiple shoe use</td>
<td>Hazard ratio: 0.614** (p=0.036)</td>
<td>No Evidence</td>
</tr>
</tbody>
</table>

* “conventional shoes” compared to “minimalist shoes”
**Statistically significant
^ Experimental group= “Traditional” shoes included: motion-control, stability or cushioned shoes; control group = stability shoes
‡ “hard shoes” compared to “soft shoes”
The primary aim of this Chapter was to assess the evidence for the effectiveness of footwear characteristics on RRI. Among the twelve RCTs included in this review, none found a statistically significant effect of the evaluated footwear characteristic and RRI. Additionally, only one RCT [43] used a valid and reliable method of assessing footwear characteristics (see Chapter 3, p 25).

Due to the high heterogeneity, empirical data from the studies in this review could not be collated. However, it is perhaps equally important to consider the theoretical evidence in order to advance the injury prevention literature [193]. A critical component to preventing injury is not only identifying the individual risk-factors at the runner’s level, but also highlight the areas where policy makers and stakeholders (government, footwear manufacturers, media/marketing, health care, and research) may be manipulating injury patterns and behaviours [16, 83]. By taking a wider view, the complex interactions of risk factors can be associated to a runner’s physical, social, psychological and emotional well-being [83, 85, 194, 195]

To assess the association between footwear characteristics and RRI, studies need to be undertaken with methodological rigour and within an appropriate system-based model (i.e. modified STAMP) [16]. Questions must address not only the plausible risk factors present in controlled conditions, but also the influences of international policies and procedures, product services, health care initiatives and shared values and opinions of runners, clinicians and researchers alike (Table 4.4) [16]. This involves identifying of the most valuable risk factors, and collaborative research efforts which contribute to a refined framework aimed towards the prevention of RRI [16].
Table 4.4: Methodological recommendations

<table>
<thead>
<tr>
<th>Methodological shortcoming</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristic identification</td>
<td>Appropriate characteristics should be identified and defined in research and clinical frameworks</td>
</tr>
<tr>
<td>Shoe Selection</td>
<td>The impacts of marketing and quality control of footwear are unknown. Studies should assess the variables associated with shoe selection (when footwear is not assigned to study participants).</td>
</tr>
<tr>
<td>Systematic nomenclature</td>
<td>When possible, studies should refrain from using self-determined nomenclature and use consensus statements or provide comprehensive measurements of footwear. Development of consensus statements towards the various footwear nomenclature is needed.</td>
</tr>
<tr>
<td>Systematic measurements</td>
<td>Appropriate reporting of footwear measurements (including rater reliability) is needed to enhance external validity.</td>
</tr>
<tr>
<td>Psychometric properties</td>
<td>Validity and reliability of footwear assessments should be regularly reported and evaluated in the literature. Predictive validity is especially needed to prevent injury associated to footwear characteristics.</td>
</tr>
<tr>
<td>Injury reporting</td>
<td>The use of established systematic injury reporting is needed to gain a global perspective of the impact of RRI. Reporting systems should include modules that allow researchers and clinicians access to training tools and resources for constructing effective methodologies.</td>
</tr>
</tbody>
</table>

4.6 Conclusion

Appropriate tests of footwear characteristics are required to determine their relationship to RRI. Clinicians and researchers can enhance footwear reporting by using established valid and
reliable assessment tools, or developing tools where assessments are lacking. Furthermore, methodologies need to be developed and implemented to provide effective communication between multiple hierarchies in the distance running system. This involves not only establishing the most important epidemiological risk-factors but also considering the theoretical influences of government policies, footwear manufacturing and marketing, professional advice, and runner perspectives.

4.7 In the next chapter

Chapters 3 and 4 have contributed to the footwear micro-system by identifying gaps in the literature where footwear research could be improved. In summary, they highlighted that current research procedures do not use consistent methods of assessing footwear characteristics, ultimately limiting the evidence of the effects of footwear on RRI. The following Chapters, 5 and 6 change directions from empirical data and explore the indirect constraints or influences of footwear on members (i.e. runners and clinicians) using qualitative approaches.
5 CHAPTER 5: EVALUATING THE FACTORS INFLUENCING RUNNERS CHOICES OF FOOTWEAR

5.1 Chapter overview

The current Chapter shifts focus from the critical analysis of the existing footwear literature (Chapters 2-4) and explores footwear from a stakeholder perspective. This study is a qualitative analysis of the factors influencing runners choices of footwear. For the purpose of this Chapter and Chapter 6, the names of the research team are included to provide transparency of data analysis and fulfil the requirements of the reporting tool: Consolidated criteria for Reporting Qualitative research (COREQ) [196].

5.2 Background

Qualitative research provides in-depth understanding of human experiences and behaviours yet is underrepresented in the context of injury research [193, 197, 198]. When considering running-injury research, only one study has explored runner’s perceptions of RRI causality [199]. That study provided valuable insight into what runners think are causative factors for RRI. Factors identified were excessive training, not warming-up or stretching, lack of strength and improper footwear. Interestingly, some of the factors identified by runners are not supported by scientific evidence [199]. Another study specific to runners perceptions of minimalist footwear [73] indicated that runners view minimalist shoes as ‘supportive’ when compared to barefoot conditions. Indeed, the term ‘supportive’ is ambiguous and the authors warrant caution when talking to runners about minimalist footwear [73]. While these studies
address the question of what runners believe, there is currently no evidence to support why these perceptions exist.

Recent literature recommends a systems-based approach to be used as a pragmatic solution to the conflicting paradigms and inconsistent data in running-related injury (RRI) research [80-83]. Systems-based research is guided by complex theoretical frameworks that describe interrelated relationships between several hierarchical levels [91, 200]. In the context of RRI, an emerging framework suggests residents of the system’s upper-tiers may include international sporting bodies, national and local governments, and equipment manufacturers [81]. The policies and procedures (or lack thereof) enforced by these bodies may then affect the goods and services provided by retailers and health care professionals, ultimately controlling the values and beliefs of the bottom-tier users, –the runners [81].

This top-down approach can be beneficial or detrimental to the health and safety of the individuals [200]. One of the primary goals of systems-based research is to strengthen methods which improve data accuracy and build comprehensive perspectives of the phenomenon in question [201]. Such methods include qualitative components where individuals (in this case, runners) are engaged in the research process. Runners’ perceptions and assumptions are regarded as imperative to the multidisciplinary prevention strategies for RRI [36, 82].

Systems-based research aims to answer the questions of why and how. This is achieved by understanding the complex interactions of the hierarchies in the system [91, 202]. In order to provide a pragmatic approach towards implementing effective injury prevention strategies, the footwear micro-system as a whole, needs to be explored from various perspectives. Given the scarcity of qualitative data derived from runners, the aim of this study was to explore the factors influencing runners choices of footwear.
5.3 **Method**

This is a qualitative study using individual and group interviews to explore the factors influencing runners choices of footwear. Ethical approval was granted for this study from the School of Physiotherapy Ethics Committee, reference: SoP/EC/2015/07 (Appendix 4) and the University of Otago Human Ethics Committee, reference: D15/375 (Appendix 5) and consultation was undertaken with the indigenous people of New Zealand, Māori (Appendix 6).

The 32-item Consolidated criteria for Reporting Qualitative research (COREQ) checklist was used to report this study (Appendix 7) [196]. The checklist contains three domains: Domain 1 focuses on research team and reflexivity. Domain 2 focuses on study design and Domain 3 on analysis and findings which encompass the content and rationale for qualitative research involving interviews or focus group techniques.

5.3.1 **Research Team**

All interviews were conducted by the primary researcher (Codi Ramsey), a female doctoral candidate in physiotherapy, with a background in physical education and a competitive runner. Prior to this study, the primary researcher had never conducted qualitative research and therefore attended several workshops and training sessions regarding theories, methods and analyses of qualitative research, which were offered through the university. Additionally, to gain experience with interviewing methods, the primary researcher undertook practice interviews under the guidance of a clinical researcher (Gisela Sole) with qualitative research experience [203-207]. A second research member, and physiotherapist with extensive qualitative research experience (Lynne Clay) [208-211] provided quality checking and helped with data coding and analysis.
The primary researcher had no prior relationships with the participants included in the study. The reasons for the research were included on the information sheet provided to each participant and the primary researcher’s background were stated prior to the commencement of each interview (Appendix 8). The primary researcher completed a bracketing exercise to establish personal values and potential bias (Appendix 9). Although bracketing is conducive to phenomenology research [212, 213] the exercise provided transparency to the study and gave the primary researcher additional training and experience in qualitative research practices.

5.3.2 Study Design

5.3.2.1 Theoretical approach

This qualitative study was guided by a general inductive approach which allows themes to freely emerge from the data [214]. Specifically, a general inductive approach allows factors influencing runners’ footwear choices to be explored with flexible guidelines. The social constructivist aspect of this theory permits researchers to interpret theories embedded in the data and include their own beliefs and experiences to bring forward a new understanding of the role of footwear in RRI treatment and prevention.

5.3.2.2 Participants

Purposive sampling was used to recruit runners from the local community of Dunedin, New Zealand. Runners between the ages of 20 and 55 years old, who were currently running more than 30 kilometres per week and not limited in their training due to injury were recruited for this study. These criteria was chosen to capture healthy recreational runners which are likely
to be more experienced with purchasing footwear than novice runners, therefore, providing a richer discussion regarding their footwear choices [215, 216].

Interested participants contacted the research team via email and were asked to complete a questionnaire sent electronically via email prior to the interview. The questionnaire included demographic data, training and injury history. Fourteen participants expressed interest in the study and provided informed written consent. While no participants dropped out of the study, interviews with two male runners were unable to be transcribed due to high levels of background noise and were not included in the analysis of this study. However, it is possible that the content discussed in these interviews may have influenced the researcher’s perceptions and subsequently the final data analysis.

Nine participants were interviewed at the School of Physiotherapy on the University of Otago campus in Dunedin, New Zealand. Other interviews took place in public businesses (n=4), and one interview was in a private home. Interviews lasted between 20 and 60 minutes, and no interview was repeated. Grouped interviews were conducted with four participants (group 1: Participants A and B; group 2: Participants X and Y) and one interview with a randomly selected participant (Participant H) was conducted with a senior researcher present to provide the primary researcher feedback on interview techniques. Some data from the interview with Participant H was derived from questions from the senior researcher.

5.3.3 Data collection

A core set of semi-structured, open-ended questions (Appendix 10) were drafted prior to interviews and adapted during the interview to deepen the data. Prompts were used to collect detailed information about the factors that influence runners footwear selections. Interview audio was
recorded and transcribed verbatim. Field notes were taken during and after each interview and included in the final analysis. After all interviews were completed, the audio recording of each interview was transcribed verbatim in Microsoft Word by the primary researcher.

5.3.4 Data Analysis

The interview transcriptions were read multiple times to familiarise researchers with the content. The primary researcher analysed all the interviews and arranged data into a coding tree, which was developed in a Microsoft Excel file. Similar text segments from the raw data were grouped together and given a descriptive label (i.e. buy shoes on sale). Labels were then grouped into category descriptions that explain the key characteristics and range of the factors influencing runners footwear choices (i.e. footwear price). Overarching themes were developed to encompass the impact of the footwear micro-system on runners choices of footwear. Quotes from the interviews to illustrate the associations to the categories were selected and agreed upon by the research team and are presented in the results. The original texts were cross-referenced to ensure accurate representation within the framework.

Two members of the research team (CR and LC) met to discuss emerging themes derived from the data. A second researcher (LC), experienced in qualitative methodology, analysed every second transcript and verified that the labels and categories were appropriate and met the aims of the study. Data saturation was determined when no new labels evolved in two consecutive interviews and was reached by the eighth interview [217]. Member checks were completed by emailing participants a summary of the categories and interpretation of the interviews (Appendix 11). Participants were asked to provide feedback and verify the
framework and summary of the results. Any feedback received was incorporated into the final results.

5.3.4.1 Exploratory open network model

An exploratory open network model [214] (Figure 5) was developed to provide a visual description of the categories and supporting labels. The open network model consists of parallel, unweighted categories which no specific sequence or hierarchy is present [214]. However, as allowed by the constructivist component of this research, the model is organised in concentric circles which through the authors interpretation of the data and feelings during interviews, represents an increasing level of influence with each category. In other words, the category in the outer circle is more influential to the runner than the categories in the inner circles.

Three main themes emerged from the data indicating that the footwear micro-system influences runners footwear choices by: economics (inner circle), other people (middle circle) and the runners own needs (outer circle). Each theme is supported with categories (white text), however, not all categories are inclusive to all runners. To provide a further grouping of the categories, they were organised into three broad labels: intrinsic factors (blue bars) which relate to the labels that describe factors originating within the runner, extrinsic factors (green bars) which relate to labels that describe factors originating outside of the runner and injury prevention strategies (yellow bars). Although Figure 5 indicates clear separation between themes, categories, and labels, there was often overlapping data which influenced runners footwear choices differently depending on the combination of factors.
5.4 Results

5.4.1 Participants

Four women and eight men runners completed interviews for this study. At the time of the interviews, all participants were healthy (not limited in their training by injuries) and running at least 30 kilometres per week (Table 5.1). Six runners reported running in more than one brand or style of shoes, depending on the activity or terrain of the training session. All participants’ shoes were less than one year old.
Table 5.1: Runner Characteristics

<table>
<thead>
<tr>
<th>ID</th>
<th>Participant Type</th>
<th>Interview Length (min)</th>
<th>Sex</th>
<th>Age Range (years)</th>
<th>Experience Range (years)</th>
<th>Kilometres Run (weekly)</th>
<th>Footwear in use</th>
<th>Footwear Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Recreational Runner*</td>
<td>27:26</td>
<td>F</td>
<td>46-50</td>
<td>0-5</td>
<td>20-30</td>
<td>1</td>
<td>0-6 months</td>
</tr>
<tr>
<td>B</td>
<td>Recreational Runner*</td>
<td>27:26</td>
<td>F</td>
<td>46-50</td>
<td>10 -20</td>
<td>20-30</td>
<td>1</td>
<td>0-6 months</td>
</tr>
<tr>
<td>C</td>
<td>Competitive Runner</td>
<td>44:27</td>
<td>M</td>
<td>36-40</td>
<td>20+</td>
<td>40+</td>
<td>1+</td>
<td>various</td>
</tr>
<tr>
<td>D</td>
<td>Professional Runner</td>
<td>44:27</td>
<td>F</td>
<td>31-35</td>
<td>10 -20</td>
<td>40+</td>
<td>1</td>
<td>0-6</td>
</tr>
<tr>
<td>E</td>
<td>Competitive Runner</td>
<td>16:20</td>
<td>F</td>
<td>36-40</td>
<td>10 -20</td>
<td>30-40</td>
<td>1+</td>
<td>0-6</td>
</tr>
<tr>
<td>F</td>
<td>Recreational Runner</td>
<td>23:17</td>
<td>M</td>
<td>50+</td>
<td>20+</td>
<td>20-30</td>
<td>1</td>
<td>6-12 months</td>
</tr>
<tr>
<td>G</td>
<td>Triathlete</td>
<td>41:14</td>
<td>M</td>
<td>18-25</td>
<td>5 -10</td>
<td>40+</td>
<td>1+</td>
<td>various</td>
</tr>
<tr>
<td>H</td>
<td>Recreational Runner†</td>
<td>58:31</td>
<td>M</td>
<td>41-45</td>
<td>0-5</td>
<td>20-30</td>
<td>1+</td>
<td>6-12 months</td>
</tr>
<tr>
<td>I</td>
<td>Competitive Runner</td>
<td>43:26</td>
<td>M</td>
<td>46-50</td>
<td>20+</td>
<td>40+</td>
<td>1+</td>
<td>various</td>
</tr>
<tr>
<td>J</td>
<td>Competitive Race walker</td>
<td>37:26</td>
<td>M</td>
<td>50+</td>
<td>10-20</td>
<td>40+</td>
<td>1</td>
<td>0-6 months</td>
</tr>
<tr>
<td>K</td>
<td>Competitive Runner</td>
<td>35:27</td>
<td>M</td>
<td>41-45</td>
<td>20+</td>
<td>30-40</td>
<td>1</td>
<td>0-6 months</td>
</tr>
<tr>
<td>L</td>
<td>Competitive Runner</td>
<td>40:36</td>
<td>M</td>
<td>46-50</td>
<td>5 -10</td>
<td>40+</td>
<td>1+</td>
<td>0-6 months</td>
</tr>
<tr>
<td>X</td>
<td>Competitive Runner *^</td>
<td></td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>Recreational Runner*^</td>
<td></td>
<td>M</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* group interviews;
† senior researcher present;
^ interview not transcribed
5.4.2 Themes

Based on interviews, three main themes emerged from the data: economics, other people and runners’ own needs. The economic theme emerged as runners expressed concerns and awareness regarding the personal and social costs associated with footwear. Runners explicitly described the other people who they seek information from regarding their footwear choices. Despite the impacts of the first two themes (economics and other people) on runners’ footwear choices, it is ultimately their own personal needs that drive the actual purchase of a pair of shoes.

5.4.2.1 Economics (inner circle)

The majority of runners are mindful of the consumption and production of footwear. Economic factors that affect their choices include the cost, availability and selection of footwear.

5.4.2.1.1 Extrinsic Factor: Cost of shoes

The price tag can influence whether a runner buys a pair of shoes and is a top concern for many runners. Participants F and H wait for a sale before buying shoes. Some runners indicated that finding shoes online can result in lower costs of footwear, however, they felt guilty for failing to support local businesses. Some runners indicated price is associated to quality and is irrelevant if they believe the shoe limits injury risk. On the other hand, Participant J feels fortunate that he finds the cheaper shoes are more comfortable and prevent injury for him.
“if they were three times the price, I’d still have to buy them, I’m really happy that they’re a cheap shoe” (Participant J)

5.4.2.1.2 Extrinsic Factor: Availability and selection

Footwear availability and selection is complicated by the plethora of available models and styles at shoe stores. Runners who are not seeking shoes with specific criteria are overwhelmed. Yet, for runners seeking a shoe with certain specifications, there seems to be a shortage in local stores.

“when I walk in there, I’m like ‘oh my gosh there’s like a bazillion shoes on the wall and you’ve gotta choose one’ and you’ve, for me I instantly go for the colour (Participant B)

Some runners resort to purchase shoes online (Participants E, G, I, J, L), travel overseas (Participants H, J), take their shoes to a cobbler to be repaired or resoled (Participants I, J) or have custom shoes designed and made (Participant C).

While unable to find the particular shoes he was looking for Participant K was pleased with one company that allowed him to take the shoes home, wear them and bring them back without any penalty. However, he would like more stores to include a trial-and-error policy for the purpose of allowing runners to test shoes that they may not have wanted to purchase due to a lack of selection.

5.4.2.1.3 Intrinsic Factor: Humanitarianism

The term humanitarianism relates to the runner’s value of the people that are involved in producing footwear or the impact of footwear disposal on the environment. Some runners
(Participants E, F, K, L) have an intrinsic concern for the ethical manufacturing of footwear or charitable use of second-hand footwear. These concerns influence their choices of footwear.

“[...] I was working in Human Rights and [...] we were working to increase [...] worker salaries [...]. One time I actually attended a factory collapse [...] and it turned out to be a footwear store and made [running shoes] so it was this massive pile of soles all over the ground outside that had fallen out of this warehouse room and it kinda made me think about what shoes I’m wearing a little bit. How I can avoid that?” (Participant L)

The awareness of international need for shoes in developing countries impacts when Participant E retires his shoes, as severely worn shoes will be of little use to people in need.

5.4.2.1.4 Prevention Strategy: Replacement

When considering injury prevention strategies, runners recognized various signals that indicated when to replace their shoes. Some runners (Participants E, F, H) used an intuitive approach and replaced shoes when pain or injury occurred. Participant A admitted to wearing shoes to the point that they were falling apart, just to avoid having to buy another pair of running shoes. She regretted waiting to buy shoes because she was injured for several months and felt if she would have bought shoes sooner, she could have avoided the injury.

Other runners (Participants B, C, D, H) track and monitor the usage and distance of their shoes using running apps on their smart-phones or GPS watches. However, there is some ambiguity about the ideal amount of usage.

“I’ve got a pair of [shoes] that I think are approaching the use by date because they've met the 500+ [kilometre] mark” (Participant H)
Runners also see the end of a shoes life as an opportunity to try new shoes and perhaps new styles.

5.4.2.2 Other people (middle circle)

The term ‘information gathering’ was used by several participants to explain the role other people have on their footwear choices. The personal decision of running footwear is developed through a process of talking to other people and learning from their experiences and opinion (extrinsic), reflecting on past experiences (intrinsic) and seeking professional advice (injury prevention).

5.4.2.2.1 Extrinsic Factor: Other runners

Participants seek advice or information from other runners about shoes regarding the fit, performance, durability, injury protection and costs. Participants (E, G, I, J, K, L) were influenced by other runners to try a new shoe brand or style. One runner (Participant G) has a strong affiliation to a particular brand of shoes because his favourite professional runner wears this brand. Some runners view other runners with similar or higher abilities as knowledgeable and trustworthy. Despite the information gathering from other people, Participants (B, F, H, I, J) feel that ultimately, their footwear decision is personal.

5.4.2.2.2 Extrinsic Factor: Media

“So yeah, I am tempted by the by the gimmicks and all these sort of new technologies, it would be way better than [shoes] from the 1980’s that’s for
Participants were suspicious towards media when shoe reviews were overly optimistic or are released without a long-enough test period. However, trends such as the barefoot/minimalist movement inspired by the book *Born to Run* by Christopher McDougall, and advanced technology “gimmicks” are enticing to some runners (Participants B, G, H, L). Participant D indicated that it would be more beneficial to runners if the marketing of footwear was directed towards performance outcomes, rather than designs.

5.4.2.2.3 Extrinsic Factor: Sales people

Participants (E, C, J) were sceptical of shoe salesmen who do not seem to care about the runners needs or know about the shoes performance and are only trying to make a sale. Participant E prefers to buy her shoes online just to avoid being pressured to try on certain shoes by the sales people. Some runners were also concerned about the use of gait-assessments and other technology used in shoe stores to prescribe a specific type of shoe.

“I think at the time I certainly favoured the outside of my foot and so they then specified the kind of shoe that would reflect that. I probably found that a little bit too prescribed and formulaic […] so, science in that regard felt more like a gimmick rather than science to me” (Participant K)

However, Participant A feels the tests and procedures of prescribing shoes has been beneficial and she has been happy with the shoes she has purchased. Furthermore, runners welcome advice when the salesmen could express their own running experiences and it was evident in their knowledge of the shoe’s performance or injury prevention qualities, particularly on off-
road terrain, runners trusted the footwear anecdotes of a sales person who had a similar injury history to themselves.

5.4.2.2.4 Intrinsic Factor: Past experiences

“I tend to stick with what feels about right, when I started running a bit more, I went for quite a lot of different shoes, different styles of shoes and these are ones, these kind of style seem to suit me the best” (Participant G)

While trial-and-error is not the influence of another person per se, runners reflected upon their past experiences in a way that their footwear choices are influenced by a former version of themselves. This seemed to be the most reliable source of information gathering among runners.

“I know that my Achilles and calf don’t like when it’s [heel-toe drop] below 8 [mm] and I feel better when I’m 8 – 10 [mm], [...] I feel more agile so I know that that’s how I feel after trial and error” (Participant C)

5.4.2.2.5 Prevention Strategy: Clinicians

Some runners rely on footwear advice from people they deem ‘professional’ i.e. coaches (Participant C, D, E, J) and physiotherapists (Participants I, K, L). Two participants (K, L) visit the same physiotherapist who regularly assesses their footwear for ‘imbalances’ and makes necessary adjustments to ensure their shoes are symmetric. These runners are highly influenced by the beliefs of the clinician, perhaps due to the clinicians past experience as a runner, and/or the perceived performance improvements as a result of the clinician’s methods.
“I get my shoes tested quite frequently with a physiotherapist [...] so you know I could feel that I could do less and [...] he would put it [in-shoe adjustments] in and I could tell quite a big difference [...] Without actually being able to feel it or see it but just because of my performance”

(Participant I)

Interestingly, runners who had not experienced an injury severe enough to seek medical attention (Participants A, B, F, G, H) did not indicate that they would speak to a health professional about footwear or injury prevention. Yet, runners who had experienced a past injury and underwent treatment (Participants C, D, E, I, J, K, L) expressed the value of a health professional in their running performance.

5.4.2.3 Runners’ own needs (outer circle)

“If a shoe is designed for pronators or designed for neutral or designed for stability and support etc., that's one thing that I guess all the guides would tell you, but to actually, to actually make a decision, a buying decision is purely personal” (Participant H)

Despite being influenced by multiple factors, most runners acknowledge that their choice of footwear is personal and is motivated by their individual preferences, and goals.

5.4.2.3.1 Extrinsic Factor: Brand and Model

The most commonly discussed extrinsic factor that influenced runners was the brand and model. Runners generally have an affiliation to a specific brand or style of shoe and prefer to use familiar footwear.
“I’ve always used [brand][...], I don’t know why, I’ve never tried any other running shoe” (Participant F)

Runners expressed being frustrated when models are changed and updated by manufacturers, reiterating potential benefits for retailers to offer trial and error periods. Runners discussed buying shoes for specific purposes (performance, comfort, terrain), so when models are changed, the runner has to re-evaluate the usefulness of the shoe. To avoid this problem, one participant admitted to buying 10 pairs of the same familiar shoe before the manufacturer changed the tread on the outer-sole.

5.4.2.3.2 Extrinsic Factor: Style and Specifications

For some runners, their footwear needs to be designed with particular specifications. For example, participants (A, C, I, K, L) discussed choosing shoes based on the amount of heel-toe drop. Participant A prefers shoes with a higher heel-toe drop and thick midsole cushioning to support her specific running style and prevent injury. Whereas Participants C, I, K, L prefer shoes with a low or zero heel-toe drop as a means of preventing injury. Other preferred footwear specifications runners often consider when looking for footwear include: tread pattern; material of upper, midsole and outer-sole; toe-box width; mass’ shoe-lace material; and colour. These specifications are preferred for multiple reasons (i.e. personal preference, comfort, performance enhancement, injury reduction/prevention) and is an area where overlapping themes are present. The individual shoe specifications are extrinsic factors by default, but the purposes for them can be translated to both the intrinsic and injury prevention categories.
5.4.2.3.3 Intrinsic Factor: Performance

All runners (except Participant F) indicated their level of preferred performance impacts their footwear choices. Runners who purchase traditional style footwear often reported choosing them for ‘support’, ‘shock absorption’ and ‘cushioning’ during running, while runners who choose minimalist style shoes discussed performance in terms of ‘power’, ‘speed’, and ‘feedback’. There is an ideology that ‘one day’ runners in traditional shoes will be experienced enough to wear minimalist shoes and perform at higher levels. This perception is supported by some experienced runners as Participant L has a sense of freedom and speed in minimalist shoes and Participant I prefers barefoot running to achieve high performance. However, this view is not exclusive to all experienced runners. Participant D feels unnatural in minimalist shoes and has experienced injuries when shoes were too minimal. Furthermore, Participant D feels advantaged by having a custom shoe that is built for performance on the terrain she runs on:

“I guess in the racing I know what I need and want and feel [...] I need a shoe that’s not gonna slip on slippery rocks or I need a shoe that’s gonna keep my foot stable when I’m on like rough terrain [...] it’s a really good shoe and I feel comfortable in it and I love how it works on the terrain that I’m running on so it’s a huge benefit [...] I can just trust the shoe on everything”

(Participant D)

Participant F is uninfluenced by the possible performance enhancements in shoes, and instead he prefers to continue enjoying the running experiences.
5.4.2.3.4 Intrinsic Factor: Comfort

The majority of runners indicated comfort is a primary factor when choosing a new pair of running shoes. Some runners (Participants F, H, J) associated comfort to a specific brand or style of shoe. The parameters defining comfort were different between participants. For example, participants B, C, J, K, and L indicated that comfortable shoes have a wide toe box to accommodate for their foot shape. Four runners (Participants A, B, E, H) assessed comfort by the amount of cushioning in the midsole and believed cushioning to be an important factor in reducing injury risk. Contrarily, participants I, K, and L feel that thick midsoles disconnect them from the ground and make them feel less steady or unable to adjust to uneven terrain. Interestingly, participant B referred to needing an adjustment period, of sometimes more than a month, before she was completely comfortable in her new shoes, whereas participants C and D could tell immediately whether they would like a shoe. Uncomfortable shoes were considered the cause of injuries for two runners:

“I could literally walk for a kilometre in a shoe that doesn’t suit me, and you know I could be, that tightness could bug me for months” (Participant C).

“I got an injury after […] I just developed calf injury using those [not preferred style of shoe] and I’ve never felt really supportive as far as running goes” (Participant K).

5.4.2.3.5 Prevention Strategy: Modify Gait

Participants A, C, E, G, K, L purchased shoes to promote proper running form, biomechanics or natural gait patterns. Runners believe the design of footwear could improve biomechanical functioning which in-turn, influences running performance. Runners choose certain footwear
designs and specifications marketed to influence biomechanical components. For example, Participant A chose her current shoes because the design is marketed to reduce her foot pronation, which she perceives as negative and indicative of injury. Participants C, I and K purchase shoes with zero millimetres of heel-toe drop to encourage a forefoot strike pattern which they believe provide better biomechanical efficiency during running and prevent injury.

5.4.2.3.6 Prevention Strategy: Multiple pairs of shoes

Some runners (Participants C, G, H, J, K, L) rotated through multiple shoes designed for specific activities, events or terrain, (e.g. training shoes vs. racing flats and, trail shoes vs. road shoes). Participant J relies on specialty footwear to achieve the desired performance from using multiple pairs of shoes depending on the task demands.

“I’ve got some flats, and I would use them in a 10k race, but you need support and flats are no use when you’re in the mountains and need a little bit of instep support” Participant J

Participants in this study were unable to specifically articulate that injury reduction was the reason they wore multiple shoes but were intuitive towards the underlying principles discussed in the study by Malisoux et al. (2015).

“I just sense that it’s [wearing multiple shoes] not putting my feet through exactly the same kind of function every time. So it’s giving them a bit of different movements, different yea, I don’t know” (Participant L)
5.5 Discussion

The present study explored the factors influencing runners’ choices of footwear. Three main categories were revealed in the analysis of the interviews with runners: (1) Economics (2) Other People and (3) Runners Own Needs. The categories were supported by descriptive labels organised into three overlapping themes: (1) Intrinsic factors (2) Extrinsic Factors and (3) Injury Prevention Strategies.

5.5.1 Context for the footwear microsystem

Understanding the behavioural risk factors associated with RRI is a critical component to develop effective injury prevention strategies [36]. By establishing why runners engage in certain behaviours (i.e. footwear choices), inadequate and deficient control and feedback structures within the RRI system can be targeted improved [81]. The current study has identified several aspects that may be impacting runners’ attitudes and behaviours toward footwear. Most notably, runners appear to be highly influenced by the perception that footwear can help them increase performance, alter biomechanics and/or prevent injury. They are persuaded by the anecdotal experiences of other runners and sometimes clinicians or salesmen with similar running goals. This in turn influences the runner to choose shoes that are designed and/or marketed with features or characteristics for specific purposes (i.e. motion control). They also discover the benefits of their preferred shoes through incidental influences such as trial-and-error.

Emerging studies utilising objective footwear measurements suggest footwear with high flexibility values can alter some biomechanical variables associated with patellofemoral pain [44] but there is no strong evidence that suggests any objective footwear characteristic
(heel-toe drop, mass, midsole material, last shape) has protective or causative qualities linked to RRI [16, 43, 218, 219]. It is possible that this lack of evidence is because the controlled environment of laboratory-based inquiry often attempts to reduce bias by providing standardised shoes, which may or may not reflect the runners real-world choices [36, 81]. Even if current research was able to confirm that a specific footwear style or characteristic can prevent (or cause) injury among runners, implementing prevention strategies is problematic due to market competition, health-care developments and, personal preferences and experiences.

Most runners in the present study indicated a level of scepticism towards various information sources. This is contrary to findings from a previous study [73]. When asked about perceptions towards minimalist and barefoot running, participants in a study by Walton et al. indicated they trust retailers and the internet over medical professionals. Whereas runners in the present study, particularly those using minimalist footwear, were quite vocal about their distrust of marketing and sale tactics such as in-store gait analyses, specifying they lack scientific evidence. As several runners wearing minimalist shoes in the current study depend on the advice and guidance of professionals (i.e. physiotherapists, coaches), it is possible that these runners view physiotherapists and coaches as reliable sources of current scientific information. The benefits of certain footwear and/or specifications expressed by retailers and shoe review articles may be inflated by profit motives; making navigating the varying opinions and a lack of unbiased evidence problematic for some runners, especially those with fewer years of running experience.

From this study, runners selection of several pairs of different shoes for specific task-related performances and injury prevention appears to be instinctual and based on common sense. However, these views are supported by current scientific literature, indicating that
parallel use of running shoes was a protective factor among recreational runners [152]. Assuming various styles (racing flat vs traditional cushioned) would provide different levels of comfort, it would be interesting to investigate the relationship of runners performance goals on the perceived comfort of their chosen footwear. Furthermore, shoe comfort has also been previously cited as a protective factor against injury [175], and a reliable clinical tool is available to assess footwear comfort [140].

Participants indicated finding the ‘right’ shoe is complicated by the overwhelming selection in stores. This is a paradox supported by literature in consumer behavioural research [220, 221], where a purchase can be bypassed due to a high quantity of choices [220]. To evade this paradox, it is suggested that company sale strategies determine an optimal number of products and variety [220, 222]. This involves considering the role of non-purchase behaviours and the consequences associated with the consumers decision-making process [220]. As participants in this study indicated, the constant changes to footwear can result in negative experiences (i.e. costly purchases, reduced performance and/or injury).

As part of a competitive, multi-billion-dollar industry, footwear manufacturers must keep-up with scientific developments and market demand [49, 172, 173]. This includes incorporating novel technologies and designs into new shoe models [173]. In New Zealand, footwear import costs are absorbed by the runners who pay higher prices to support local business compared to buying cheaper shoes from overseas or online suppliers [223]. However, due to the import costs, retailers are careful to only import footwear that will be profitably sold [223], limiting the availability of some brands, styles, and sizes –an impact felt by some participants in this study. Retailers should make calculated decisions regarding their stock to find a balance between consumer familiarity and market trends [220].
5.5.2 Clinical implications

This research highlights how health and safety of runners is impacted by upper-level hierarchies within the RRI system. Currently, no systematic feedback structure is in place for runners to communicate with footwear manufacturers and/or designers. Clinicians could help fill this gap by assessing footwear using objective measurements and publishing findings associated with RRI in clinical reports.

Runners in the present study value clinical procedures and advice. This is contradictory to the findings of a previous qualitative study, in which runners prefer information from the internet over that of health professionals [73]. However, runners are likely to only interact with clinicians after experiencing an injury. Walton et al. (2016) suggested health professionals should emphasize their practical knowledge of running and injury prevention to gain credibility among runners [73]. While credibility is not an issue among the runners in this study, clinicians may contribute to injury prevention within the running-injury system by participating in educational forums and providing advice to novice and non-injured populations. Reiterating the suggestion by Walton et al. (2016), clinicians should be clear in their instruction and guidance when discussing relative terms such as ‘comfort’, ‘support’ and ‘fit’ [73]. This will allow the runner to make informed decisions regarding their footwear and continue to build trust in the clinician.

5.5.3 Research implications

It is likely that as novice runners gain experience and become recreational and competitive runners, their knowledge about footwear increases. Through multiple strategies and experiences, runners develop perceptions about how to choose the most appropriate
footwear for their needs. Unfortunately, one experience often endured by runners is injury [17, 19, 27, 136, 147, 157], therefore increasing their risk of future injury [17, 149, 188]. Future qualitative inquiry is needed to understand the base knowledge of novice runners and establish effective prevention strategies that reduce the risk of the initial injury.

While runners in this study seek advice from physiotherapists, it is perhaps important to underpin the perceptions clinicians have towards footwear in their assessment and treatment of RRI. This would allow a deeper understanding of why some runners rely heavily on clinical advice and footwear monitoring to prevent injury. It may also illustrate effective methods used in clinical practice that are not yet considered in research objectives.

### 5.5.4 Strengths and limitations

The number of analysed interviews in this study (n=12) is considered a moderate sample size [224] for exploratory qualitative research. Although there were only four females, the participants represented a wide range of running-experience (0-20+ years) and shoe styles/brands. We aimed to capture the perspectives of healthy recreational runners, therefore, the perspectives of novice and injured runners are not represented in our analysis.

The data derived from this research is strengthened through dual-researcher analysis. Categories and themes were approved and checked by a second researcher with qualitative research experience. The primary researcher performed a bracketing exercise before commencing interviews. This provides transparency between data derived from participants and the thoughts of the interviewer [212, 213]. Themes, labels and categories were confirmed by a second researcher with varying views to those of the primary researcher, therefore reflecting a balance of opinions. Stake-holder checks were completed by sending all
participants a summary of the results to the email they provided on the questionnaire. Participants were encouraged to respond with any comments or suggestions, which were incorporated into the final analysis.

5.6 Conclusion

The present study contributes to an area of footwear research that has previously received little attention. Runners are affected by economic factors and other people when choosing footwear to meet their own needs. Acknowledging the factors influencing runners’ choices of footwear allows for a deeper understanding of the footwear micro-system and may contribute to developing appropriate injury prevention strategies.

5.7 In the next chapter

While the previous chapters have evaluated the footwear micro-system among research (Chapters 2-4) and runners (Chapter 5), the next chapter explores the remaining population of interest, clinicians. Chapter 6 continues qualitative research to assess clinicians’ perceptions of footwear in the assessment and management of RRI.
6 CHAPTER 6: DOES FOOTWEAR MATTER? EVALUATING THE CLINICAL PERSPECTIVES OF FOOTWEAR

6.1 Chapter overview

The previous chapter presented the factors influencing runners’ choices of footwear. The aim of the current chapter was to evaluate clinicians’ perspectives of footwear in the assessment and management of RRI. Together, these Chapters address some of the indirect effects of footwear in the footwear micro-system.

6.2 Background

As described in Chapter 5, qualitative inquiry is an important method to understanding the complex interrelationships of RRI [36, 80, 81]. In the previous chapter, runners identified several factors that influence their footwear choices. One such factor was the advice given by other people: clinicians, coaches, shoe store salesmen and other runners. Some runners who had experienced a previous injury were reliant upon the continued advice and monitoring from their physiotherapist. However, this view is not supported in other research as, Walton (2006) found runners were more inclined to gather information from the internet or other non-professional sources [73].

Current literature regarding clinicians opinions and treatment of injury is limited to only a one qualitative study which is centred around elite athletes (including runners) [225]
and a clinical commentary on clinicians use of in-shoe orthoses to manage patellofemoral pain (PFP) [226]. Clinicians view improper training and poor techniques as the main factors responsible for injury in elite athletes [225] and are reluctant to use orthoses when treating patients with PFP [226]. However, conflicting paradigms and theories [68, 227] as well as a lack of evidence-based literature [131], provide clinicians with little support of their methods and beliefs. This is likely a major problem in the epidemiological research field for the management and prevention of RRI. These drawbacks exemplify areas where systems-based research could help identify areas in need of strengthening [80, 81, 83, 91].

Through the use of qualitative inquiry, we can understand the motivations and goals underpinning the behaviours which may be affecting RRI treatment and prevention strategies [81]. From here, the complex involvement of one individual variable—footwear—can applied to the footwear micro-system [91] and help identify clinician’s role in the control and feedback mechanisms [81] of RRI treatment and prevention. Therefore, the aim of this study, was to understand clinician’s perceptions of footwear when assessing and managing patients with RRI.

6.3 Method

This qualitative study uses similar methodology as used in Chapter 3, and the 32-item Consolidated criteria for Reporting Qualitative research (COREQ) checklist was used to report this study (Appendix 7) [196]. The School of Physiotherapy Ethics Committee (Appendix 4) and the University of Otago Ethics Committee (Appendix 5) granted ethical approval for this study. The information sheet (Appendix 12) for this study contained the reasons for research and was distributed to all participants prior to interviewing.
6.3.1 Research Team

The primary researcher (Codi Ramsey) is a female doctoral candidate in physiotherapy and conducted all interviews with the clinicians in this study. Interviews from Chapter 3 and the current Chapter were conducted over the same time period, therefore the workshops and trainings attended prior to commencing data collection in Chapter 5 (see section 5.3.1) were also applicable to the training for the study in the current Chapter. A second researcher and physiotherapist with extensive qualitative research experience (Lynne Clay) provided quality checking and data coding during the early stages of this study.

The primary researcher had no relationships with the clinicians before this study. Additionally, the primary researcher informed participants about her background as a physical education teacher and doctoral candidate based at the School of Physiotherapy before beginning the interviews with the clinicians.

6.3.2 Study design

6.3.2.1 Theoretical approach

Following the same approach as Chapter 5, a general inductive approach stemming from social constructivist theory was used to guide the analysis of this study [214]. It has flexible guidelines that allow the researcher’s thoughts and beliefs to be incorporated into the analysis in order to provide a rich discussion surrounding the role of footwear in the assessment and management of RRI.
6.3.2.2 Participants

Purposive sampling was used to recruit registered physiotherapists and podiatrists in New Zealand who treated at least one patient with RRI in the past 12 months. These criteria were used to capture clinicians that likely evaluate footwear when assessing and treating runner, This ensured that these participants can contribute to the study aims with rich data [215, 216]. Potential clinicians were contacted through email, which were retrieved from publicly available websites. An advert was distributed in the New Zealand Journal of Physiotherapy a peer-reviewed publication available to members of Physiotherapy New Zealand (PNZ).

Clinicians that expressed interest in the study were asked to complete a questionnaire with demographic information including: participant’s clinical settings (private, hospital etc.), years as a clinician, and patient type and load. This allowed for sub-group analysis if themes and categories were consistent among clinicians with similar demographics. Nine clinicians contacted the primary researcher and eight completed the demographic questionnaire, provided informed consent and participated in the study.

Six participants were interviewed in-person at the participants place of business (n=5) and the School of Physiotherapy at the University of Otago (n=1). One participant lived in another New Zealand city and completed the interview using a web-based video platform (ZOOM Video Communications Inc., San Jose, California) which allowed the audio and video to be recorded and stored in a secure file. All interviews lasted between 20 and 60 minutes, and no interview was repeated. Six interviews were conducted with only the primary researcher and the clinician present and one interview was conducted with two clinicians (Participants 1 and 2) and the primary researcher.
6.3.2.3 Data collection

The primary researcher interviewed all participants using a core set of semi-structured, open-ended questions and prompts (Appendix 13). Questions aimed to collect detailed information about the methods of and reasons for the clinician’s assessments of injured runners. The questions were drafted before undertaking interviews and were adapted during the interview to increase data richness. Audio recordings from the in-person interviews were recorded and transcribed verbatim. Field notes from the interviews were included in the final analysis. After all interviews were completed, the audio recordings were transcribed verbatim by the primary researcher.

6.3.3 Data Analysis

The bracketing exercise described in Chapter 5 (Appendix 9) was also used as an exercise for the current Chapter. The exercise was completed by the primary researcher prior to commencing interviews, to identify and document any bias and pre-judgements regarding how clinicians assess and manage footwear for runners with RRI [212, 213].

Similar to the methods used for analysis in Chapter 5, the primary researcher read the interview transcriptions multiple times to become familiar with the content. A coding tree was developed from labels that were assigned to similar text segments from the raw data. Labels were then grouped into categories and themes emerged from the categories. Clinician’s perspectives of footwear in the management of RRI are represented by three main themes: inconsistent techniques for assessing footwear, barefoot tells the story and footwear for treatment. The themes are supported by categories and labels that suggest clinicians have
varying views about the importance of footwear in the management of RRI. A summary of the themes and subthemes are presented in Table 6.2.

The clinicians in this study were asked about their step-by-step procedures when assessing a patient with a suspected RRI. All clinicians described subjective and objective patient assessments which varied in test type and sequence but could be grouped into three main topics: personal attributes, training history, and other. Among the ‘other’ category includes assessment of footwear. The actual amount of data derived regarding clinician’s perceptions of footwear was minimal when compared to data from the ‘personal attributes’ and ‘training history’ categories. With the exception of one clinician (Participant M), footwear was only assessed if the shoes were brought in by the patient or only after ruling out risk factors associated to the individual runner. Quotes from the interviews were used to support the categories and labels and illustrate the perceptions clinicians have towards footwear.

A second researcher (LC) confirmed the identified labels and helped develop appropriate categories. Consultation with an expert qualitative researcher (BD) helped conceptualise the overall themes. The views and values of the two researchers varied and therefore reflect a balance of opinions in this research. All participants were emailed a summary of the results and asked to provide comments or suggestions regarding the content and categories of the research. Original texts were cross-referenced, and member checks were completed to ensure correct interpretation of the data. Data saturation was determined a priori when no new labels evolved in two consecutive interviews and was reached after the sixth interview.

Additional consultation for the data analysis and theme development of this Chapter was sought from an expert in qualitative research methodologies (Associate Professor Ben Daniel).
6.4 Results

6.4.1 Participants

Three female and four male clinicians participated in this study (Table 6.1). Six clinicians were physiotherapists, and four worked in private practice, one worked in a hospital clinic and one worked in a university clinic. The other clinician was a podiatrist working in a private practice. All clinicians had 10 or more years of experience and had treated at least one runner with RRIs in the last 6 months.
Table 6.1: Clinician Characteristics

<table>
<thead>
<tr>
<th>ID</th>
<th>Participant Type</th>
<th>Interview Length</th>
<th>Sex</th>
<th>Age (range years)</th>
<th>Clinical Experience (range years)</th>
<th>Patients Weekly Volume</th>
<th>Type</th>
<th>Conditions treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>Physiotherapist</td>
<td>24:41</td>
<td>M</td>
<td>51-60</td>
<td>9 - 15</td>
<td>10 -20</td>
<td>Ath, Age</td>
<td>Chronic</td>
</tr>
<tr>
<td>N</td>
<td>Physiotherapist</td>
<td>40:17</td>
<td>F</td>
<td>31-40</td>
<td>9 - 15</td>
<td>20+</td>
<td>Ath, Age, Pt, Dd, Ch</td>
<td>Chronic, Acute, Post-surgical, gradual onset</td>
</tr>
<tr>
<td>O</td>
<td>Physiotherapist</td>
<td>40:17</td>
<td>F</td>
<td>41-50</td>
<td>16-25</td>
<td>20+</td>
<td>Ath, Age</td>
<td>Chronic, Acute, Post-surgical</td>
</tr>
<tr>
<td>P</td>
<td>Physiotherapist</td>
<td>37:49</td>
<td>M</td>
<td>51-60</td>
<td>25+</td>
<td>20+</td>
<td>Ath, Pt, Dd</td>
<td>Chronic, Acute, Post-surgical</td>
</tr>
<tr>
<td>Q</td>
<td>Physiotherapist</td>
<td>53:40</td>
<td>M</td>
<td>41-50</td>
<td>20+</td>
<td>20+</td>
<td>Ath, Pt, Dd</td>
<td>Chronic, Acute, Post-surgical</td>
</tr>
<tr>
<td>R</td>
<td>Physiotherapist</td>
<td>26:52</td>
<td>F</td>
<td>31-40</td>
<td>9 - 15</td>
<td>20+</td>
<td>Ath, Pt, Dd</td>
<td>Chronic, Acute, Post-surgical</td>
</tr>
<tr>
<td>S</td>
<td>Podiatrist</td>
<td>48:41</td>
<td>M</td>
<td>41-50</td>
<td>9 - 15</td>
<td>10 -20</td>
<td>Ath, Pt, Dd</td>
<td>Chronic, acute, post-surgical</td>
</tr>
</tbody>
</table>

Patient type codes: Ath=athlete, Ag=ageing, Pt=post-trauma, Dd=degenerative disorders, Ch=children
6.4.2 Theme 1: Inconsistent footwear assessment techniques

It appears clinicians do not have well established or supported methods for assessing patients’ footwear. Most commonly, clinicians described using visual assessments to evaluate various footwear features. Clinicians looked at their patient’s shoes to determine the “fatigue...support features...material...lacing patterns and fit” (Participant S), “quality” (Participant R), “type” or “style” (Participants Q, R, S, O, P) and “wear patterns” (Participants R, S, P). Information from these assessments helped the clinician determine whether the patients shoes were “too stiff or generally too loose” (Participant S), the “overall condition” of the shoe (Participants M, O, R) and whether they were “appropriate” for the runner (Participants N, P, Q, R, S).

Most clinicians were unable to describe the criteria they use to make clinical decisions about their patient’s footwear. For example: Participant S discussed relying on “just experience” because he is “unaware of any sort of tool” to assess if minimalist footwear is suitable for a patient. Participants O, P, Q and S mentioned “comfort” as an important component of the participant’s footwear and “plays a key role in injury prevention” (Participant S). However, none of the clinicians interviewed in this study, indicated they measure footwear comfort, despite the availability of a valid clinical comfort assessment tool [140].

Only one clinician (Participant M) described using objective methods to assess “footwear asymmetry”. The specific measurements of the inner-, mid- and outer-sole thickness and hardness provide a single cumulative score that indicates the mediolateral asymmetry as a result of either the shoe “design [and/or] degradation”. This footwear asymmetry assessment was developed by Participant M and is performed as a primary patient assessment. The views by Participant M toward assessing footwear asymmetry presents a
novel perspective of the relationship between the design and degradation of footwear and RRI. Using objective measurements to assess footwear characteristics do not appear to be considered by other clinicians in this study.

6.4.3 Theme 2: rely on patient’s barefoot performance

Participants in this study reported assessing the patient barefoot while performing static and/or dynamic movements, i.e. “single leg squats” (Participants M, N, Q, S). Over 70% (5 out of 7) of the clinicians (Participants N, P, Q, R, S) suggested that the patient’s movements while barefoot provide a clear picture of the foot and ankle biomechanics while shod, during running. Participant P used the patient’s barefooted posture to “match” their foot to an appropriate shoe. Participant R prefers to “leave [the shoe] out of it” indicating that she only assesses the patient while barefoot and does not evaluate the patient while shod. Participants (Q, S, O) assess patient’s while shod but only to evaluate their gait patterns.

Interestingly, clinicians also expressed that the patient is injured because “it’s [shoe] absolutely clapped out” (Participant Q) or the patients are “wearing a crap shoe” (Participant R). However, as identified in Theme 1, clinicians have limited criteria to determine when a shoe is harmful to the patient. Participant S addressed the apparent gap between assessing the patient while barefoot and linking the results to the patient’s performance while shod. Participant S reflected and suggested the following:

“It’s not necessarily going to be overly indicative of what they’re doing when they’re running if they run in shoes and they were assessed in bare feet. I’m going to start doing that now [assessing patients in shoes]” (Participant S)
It is worrying that Participant S rapidly changed his perception towards his assessments of patients during this interview. It indicates that footwear is not thoroughly thought about when assessing injured runners.

Only one Participant (Participant M) explained a method and clinical application for assessing patients while barefooted and shod. Participant M assesses the patient’s movements of the same dynamic tasks while barefoot and shod. This allows him to compare “what their body does and then ... what it does when they put their shoes on... is it [shod movement] exactly the same or does it look very different” (Participant M).

6.4.4 Theme 3: Footwear for treatment

All clinicians in this study prescribe uninjured runners new footwear as a form of treatment. Despite inconsistencies in the assessment of footwear and the patient, clinicians seem to arrive at the same treatment strategy: prescribe new footwear. Some clinicians use the strategy as a “process of elimination” (Participant P) indicating that replacing footwear may be “all they [patient] needed” (Participant O). Participant Q justifies the financial expense of buying new shoes by telling patients that “they would spend more money on physiotherapy than they would on footwear”. Participants O, Q, R and S also have established relationships with local footwear retailers and refer patients to a specific store. Often the referral is accompanied by a suggested footwear style or model that is based on the clinician’s assessments, but ultimately, the clinician’s “trust the guys down there [shoe store]”.

Participant M argues that replacing just the running-shoes is not enough, because patients likely spend most of their day in other and multiple pairs of shoes. Indicating that the possible asymmetry present in the running shoes may also be present in their other-shoes and may increase the recovery time from the injury. Rather than referring patients on, Participant
M will adjust the footwear by “grinding or adding a 1 mil [millimetre] wedge to correct or balance footwear”. If the patient’s footwear is beyond repair and needs to be “scrap[ed]” or “replace[d]”, Participant M helps patients choose replacement footwear by accompanying them to the store and measuring shoes to ensure they are designed with minimal asymmetry. This allows patients a chance to wear shoes that are not skewed by design. Furthermore, Participant M continues to monitor the wear and degradation of the shoes as the runner wears them and provide treatment or rebalancing of the shoes as needed. Again, the views expressed by Participant M are novel and do not seem to be shared by other clinicians in this study.

Table 6.2: Themes and sub-themes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Subtheme</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconsistent footwear assessment techniques</td>
<td>Visual assessments</td>
<td>Signs of fatigue, wear patterns, improper fit</td>
</tr>
<tr>
<td></td>
<td>Clinical criteria</td>
<td>Experience, intuition, patient comfort</td>
</tr>
<tr>
<td></td>
<td>Objective tools</td>
<td>Total asymmetry score tool</td>
</tr>
<tr>
<td>Rely on patient’s barefoot performance</td>
<td>Assess barefoot only</td>
<td>Dynamic and static tests-relate to shod condition</td>
</tr>
<tr>
<td></td>
<td>Compare barefoot and shod</td>
<td>Dynamic tasks are compared</td>
</tr>
<tr>
<td>Footwear for treatment</td>
<td>Prescribe new running shoes</td>
<td>Process of elimination, cheaper than therapy, referral to specific shoe store</td>
</tr>
<tr>
<td></td>
<td>Balance all shoes</td>
<td>Patients wear many shoes per day/week, correct unbalanced with wedges or grinding</td>
</tr>
</tbody>
</table>
6.5 Discussion

This study aimed to explore clinician’s perceptions of footwear in the assessment and management of RRI. Clinician’s attitudes towards footwear are portrayed in three main themes (1) inconsistent footwear assessment techniques (2) rely on patient’s barefoot performance and (3) footwear for treatment.

Clinicians recognise that footwear is likely involved in the aetiology of RRI. However, most clinicians had difficulties assessing footwear. This could be due to the complexity of footwear assessments (i.e. footwear assessment tool [23]). Furthermore, it appears that clinicians assess patients while barefoot, but fail to connect the relationship to footwear by not assessing the patient doing similar tasks in barefoot and shod conditions. Indeed, replacing the patient’s footwear is among the top treatment strategies as it is cost effective and may be a simple treatment compared to other interventions described (i.e. strapping, dry needling, or gait retraining).

One Participant (Participant M) described a novel method of assessing footwear which identifies asymmetric patterns that are a result of design or degradation of the shoe. The information obtained from the footwear assessments can then be used to balance the patient’s footwear, so that the patient’s performance of dynamic tasks is similar when shod and barefoot. These views and practices do not seem to be shared by other clinicians but may be useful in future research and clinical applications.

6.5.1 Footwear in the running-injury system

The views expressed by most of the clinician’s in this study represent a ‘person-centred’ approach to identifying injury.
“when you point out the 7 or 8 different strategic errors they've [runners] made, it might be the shoes that just kinda tip them over the edge”

( Participant S ).

Holden (2011) explains that it is a psychological tendency and/or industry norm to ‘blame’ injury on human-error [95]. Although footwear is an extrinsic factor, clinicians relate the injury to the footwear the runner chose, or the wear patterns caused by the runners’ habits. Shifting the focus of injury causation from person-centred to system-centred, requires evaluating how the system itself is influencing injury [81]. As such, understanding the psychological tendencies of clinicians is essential to implementing paradigm shifts and prevention strategies.

The current study revealed that most clinicians are person-centred in their assessment and treatment of RRI. However, one clinician indicated a system-centred focus in which footwear was objectively evaluated and corrected or ‘balanced’ (if possible), regardless of the runner’s inherent biomechanics, genetics or training regimens. It could be construed that Participant M is still person-centred but is instead ‘blaming’ footwear companies for injury rather than the runner. However, it needs to be pointed-out that the Participant M monitors a specific characteristic –mediolateral asymmetry– in all footwear (athletic, dress shoes, casual shoes etc.) which is caused through design and degradation, and determines treatment based on the footwear asymmetry scores. By assessing the mediolateral asymmetry of footwear, Participant M is addressing injury from a systems-based perspective by:

1. Considering non-human influences into the relationship of RRI
2. Providing a resource/tool that could be implemented into control and feedback relationships within the footwear micro-system
3. Offering new knowledge about how to monitor and prevent mechanisms associated to RRI
The perceptions of the Participants in this study are useful to understanding the role clinicians play in the footwear micro-system. However, Participant M introduced novel ideas where the footwear micro-system could be developed and strengthened. Still much work remains for clinicians and researchers to implement effective prevention and treatment strategies which will reduce the risk of RRI.

6.5.2 Approaching the running-injury system

This study suggests clinicians may fail to consider the effects of footwear on RRI and instead focus on the inherent faults of the runner. Given that most the Participants in this study completed their clinical training before the emergence of the current footwear debate (established approximately in 2004) [68], it is possible that clinicians are reluctant to assess footwear, despite their training and skills [226]. Additionally, scholarly journals offer little clarity and lack evidence for practice [131]. When assessing patients with RRI, clinicians could compare dynamic performance tests of shod and barefoot conditions. This may provide insight into how footwear alters neuromuscular feedback [124]. Further, measuring specific components of footwear (i.e. mediolateral asymmetry) may contribute to knowledge about which footwear conditions are attributed to injury. It is also important for clinicians to publish clinical reports based on findings of footwear measurements and patient injury as this may help direct research initiatives.

Clinicians are one of the links between runners and members of the upper level hierarchies of the footwear micro-system and the running-injury system (i.e. footwear manufacturers, government funding agencies, sporting organisations, research bodies) [81]. It is important for clinicians to take an active role in controlling what information runners receive regarding footwear. This may include establishing relationships with local footwear
retailers and providing trainings on how to assess and prescribe footwear using objective measurements. It may also involve hosting workshops for runners to learn when to recognise and how to replace worn footwear. Again, publishing clinical outcomes (reduced injury rates, number of visits pertaining to assessing footwear as prevention, etc.) would help establish effective practices for clinicians in the control structure of the running-injury system. Additionally, reporting findings may draw attention to defective or insufficient areas of footwear manufacturing, delivering a successful feedback mechanism.

6.5.3 Research implications

Few qualitative studies have been conducted in the field of running-injury research. While this study provides a set of data relative to clinicians in New Zealand, further research is needed to establish methodologies and perceptions of other populations of clinicians. Additionally, exploring questions regarding how clinicians may be shaping the footwear micro-system and running-injury system is important to establishing effective control and feedback mechanisms. Questions may include: what and how clinicians seek continuing education, workshops for community runners, and reporting of injuries and assessments.

Objective footwear assessments may provide an alternative and complementary technique enabling control and feedback mechanisms to be established within the footwear-micro-system. Despite the availability of several footwear assessment tools in the literature (Chapters 2 and 3) the clinicians included in this study did not routinely utilise them. Future research is needed to continue to develop footwear assessment tools to support clinical and research procedures. Footwear assessment tools need to be reliable and feasible for use in multiple settings (i.e. field research or clinics). This allows for practical and diverse use of the tool.
6.5.4 Strengths and Limitations

Interviews with seven clinicians were analysed in this study and is considered a small but acceptable sample size for exploratory qualitative research [224]. Data saturation was achieved after the sixth interview [217], however, no other clinician shared similar views with Participant M. It should be noted that Participant M specialised in footwear assessments in his clinic and has completed a PhD thesis on the theories and methodologies he uses in his clinical practice. It is possible that the expertise of Participant M may unintentionally create the shaman effect in this study [228]. The shaman effect refers to a participant with specialised knowledge on a topic and can overshadow the results and data [228]. Methods to overcome this potential limitation is to include participants with varying interests in the topic or using focus group interviews to create an unstructured dialogue between participants [228].

Three female and four male clinicians represented a wide range of experiences, clinical backgrounds and education. Clinicians with less than 10 years of experience did not express interest in this study, therefore, the results may not reflect the views held by more novice clinicians, who may have been introduced to alternative theories about footwear and/or injury systems in recent years of training. Additionally, no running coaches were involved in this study, and also may have differing perspectives toward the use of footwear in managing RRI.

6.6 Conclusion

The present study revealed that most clinicians lack assessment tools and clinical reasoning when assessing and prescribing footwear among patients with RRI. This may be due to a person-centred approach towards the aetiology of RRI. Shifting to a more direct focus of the
effects of footwear on RRI requires a systems-centred approach which informs control and feedback mechanisms within the footwear micro-system. Indeed, the use of footwear assessment tools in clinical settings may contribute to a systems-centred approach to treating and preventing RRI.

6.7 *In the next chapter*

Chapters 5 and 6 have presented ways footwear may be indirectly influencing RRI in the footwear micro-system. The next Chapter shifts focus again to address the last systems-based research objective: present potential intervention strategies to prevent RRI (see section 1.3.2, page 12). Chapter 7 will evaluate the reliability of the footwear asymmetry score tool, presented by Participant M in the current Chapter.
CHAPTER 7: RELIABILITY OF THE FOOTWEAR TOTAL ASYMMETRY SCORE TOOL

7.1 Chapter Overview

This Chapter reports essential psychometric properties (within-rater, between-rater and between-day reliability) for a novel method of assessing footwear asymmetry: the footwear total asymmetry score tool (TAS). Chapter 1 explains how the TAS was introduced to the aims of this thesis and the rationale for using the TAS within the footwear microsystem. Chapters 2-4 highlighted a gap in the literature where objective footwear assessments are missing from studies of footwear and RRI. This Chapter builds on the findings from the interviews with clinicians in Chapter 6 and advances the knowledge in the footwear microsystem by introducing a method of footwear assessment that may not be currently considered by clinicians.

Acknowledgement: This chapter is derived from an article published in Footwear Science, June 14, 2018, copyright Taylor & Francis, available online: tandfonline.com/10.1080/19424280.2018.1478888 [130].

7.2 Introduction

Despite scientifically advanced running shoe designs, running-related injuries affect up to 79% of runners [16, 149]. Footwear is considered a risk factor for RRI [16, 149, 188, 199] thus analysing footwear characteristics is critical to future injury prevention strategies [81, 229]. Footwear mediolateral asymmetry is the result of design and/or degradation and is commonly present in running shoes. The components of a shoe that contribute to this asymmetry are
the outer, mid and innersoles [165]. The durability after sustained loading affect each component differently, amplifying or neutralising asymmetry and is critical to the long-term reliability of the shoe. Footwear with designed asymmetry such as stability shoe with harder medial midsoles, often degrade quickest on the lateral, softer midsole [165]. This increased asymmetry may contribute to ankle inversion injuries [183], increase medial knee joint stress [61, 230] and joint loading at the hip, knee and ankle along with peak mediolateral and vertical ground reaction forces [55]. Sole et al [128] found small (1 mm) mediolateral changes to the foot-ground interface, significantly decreased performance of a dynamic single-legged task [128]. Additionally, aged or worn footwear induce compensatory movements [111], reduce shock absorbing abilities [184, 185], and influence lower-limb stability [184]. Although not supported by data, the concepts regarding a runner’s preferred movement path [227], it is possible that the effects of aged, worn or asymmetric footwear could compromise the runner’s preferred movement pathway, increasing loading and may result in injury [227].

Current injury rates suggest that shoe design and prescription are not evidence-based [131]. The importance of quantifying mediolateral asymmetry is reflected in past and current research of footwear designs which have applied medial or lateral interventions without considering the current status of the individuals footwear [230-234]. Additionally, research has failed to assess how particular characteristics, such as asymmetric heel degradation, may mediate the effects of experimental conditions—Using valid and reliable tools to assess footwear asymmetry may help identify critical thresholds important in injury prevention. Accordingly, adequate within-rater and between-rater reliability is essential before establishing relationships to injuries or treatments. Between-day reliability is essential as shoes are progressively assessed over time.

The footwear total asymmetry score (TAS) is an objective measure of the mediolateral differences of thickness and hardness of the inner-, mid- and outer-sole [165]. It provides a
composite score of mediolateral asymmetry as a result of degradation and/or design of the shoe at the rearfoot and forefoot. Previous studies have assessed footwear asymmetry and found decreased dynamic performance and stability among simulated medial and lateral shoe wear [128] and adaptive strategies during gait among people with laterally biased footwear [170]. Furthermore, the TAS has been comprehensively described in a previous published article [165] but its use is limited to only studies in which the tools developer (C.C. Sole) was listed as an author or co-author (Google Scholar citations search 20, September 2018). It is likely that there was measurement error when using the digital callipers and durometers described in these previous studies. Additionally, the authors did not report the reliability of the measurements or the raters when assessing the TAS. Additionally, the reliability of the TAS has not yet been established in the literature. The aim of this study was to determine the within-rater, between-rater and between-day reliability of the TAS for use in clinical and research settings.

7.3 Method

Four raters (two experienced and two novice) assessed the mediolateral asymmetry of 10 individual shoes in this cross-sectional reliability study. One experienced and one novice rater assessed the same shoes on two different days. There were no human participants; therefore, ethical approval was not required.
7.3.1 Raters

The novice raters were a physical education coach/instructor and a clinical physiotherapist with five and four years’ experience, respectively. Both expert raters had 20+ years of clinical and academic research. The TAS tool was developed and described by the one of the expert physiotherapists [165], [124] and also incorporates the measure as part of routine patient assessments. All raters were trained by the tool developer and practice measurements were conducted before official recording commenced.

7.3.2 Footwear

TAS scores were determined for ten un-paired running shoes, varying in style, brand and age (Table 7.1) from six different individuals. This allowed the raters to assess asymmetry from a spectrum of typical footwear designs and wear patterns that would be presented in clinical settings. Footwear design included traditional, thick, cushioned midsoles with elevated heels, arch supports and/or motion control features, and shoes of minimalist design, lightweight, highly flexible and low heel-toe drop [22]. Additionally, some shoes in this study had prescribed orthotic insoles which were assessed identically to standard insoles. Consequently, these were assessed in the same way as all standard footwear innersole but improved the external validity of our findings. The selected footwear were not worn during or between assessments.
Table 7.1: Footwear Characteristics.

<table>
<thead>
<tr>
<th>Shoe</th>
<th>Brand/Model</th>
<th>Classification</th>
<th>Usage (months)</th>
<th>Right/Left</th>
<th>Orthotics Present</th>
<th>Mediolateral Asymmetry*</th>
<th>Thickness (mm)</th>
<th>Hardness (Asker-C)</th>
<th>TAS (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>RF (M) FF (M) RF (M) FF (M) RF (M) FF (M) RF (M) FF (M)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Puma/Fast 500</td>
<td>Neutral</td>
<td>6-12</td>
<td>Right</td>
<td>Yes</td>
<td>RF (M) FF (M)</td>
<td>1 (M)</td>
<td>1 (M)</td>
<td>1 (M)</td>
</tr>
<tr>
<td>2</td>
<td>Nike/Voomero v4</td>
<td>Stability</td>
<td>0</td>
<td>Right</td>
<td>No</td>
<td>RF (L) FF (L)</td>
<td>2 (L)</td>
<td>1 (L)</td>
<td>9 (M)</td>
</tr>
<tr>
<td>3</td>
<td>Asics/Noosa Tri 10</td>
<td>Stability</td>
<td>6-12</td>
<td>Right</td>
<td>No</td>
<td>RF (L) FF (N)</td>
<td>1 (L)</td>
<td>0 (N)</td>
<td>8 (L)</td>
</tr>
<tr>
<td>4</td>
<td>Asics/GT 2000</td>
<td>Stability</td>
<td>0</td>
<td>Left</td>
<td>No</td>
<td>RF (L) FF (L)</td>
<td>3 (L)</td>
<td>1 (L)</td>
<td>12 (L)</td>
</tr>
<tr>
<td>5</td>
<td>Nike/Pegasus 30</td>
<td>Neutral</td>
<td>12+</td>
<td>Right</td>
<td>Yes</td>
<td>RF (L) FF (M)</td>
<td>2 (L)</td>
<td>2 (M)</td>
<td>3 (L)</td>
</tr>
<tr>
<td>6</td>
<td>Saucony/Prestige</td>
<td>Neutral</td>
<td>12+</td>
<td>Left</td>
<td>No</td>
<td>RF (N) FF (M)</td>
<td>0 (N)</td>
<td>1 (M)</td>
<td>2 (M)</td>
</tr>
<tr>
<td>7</td>
<td>Pearl Izume/Trail M2</td>
<td>Neutral</td>
<td>6-12</td>
<td>Left</td>
<td>No</td>
<td>RF (M) FF (N)</td>
<td>1 (M)</td>
<td>0 (N)</td>
<td>8 (L)</td>
</tr>
<tr>
<td>8</td>
<td>Asics/Gel Noosa Tri 9</td>
<td>Stability</td>
<td>6-12</td>
<td>Left</td>
<td>No</td>
<td>RF (L) FF (M)</td>
<td>1 (L)</td>
<td>2 (L)</td>
<td>14 (L)</td>
</tr>
<tr>
<td>9</td>
<td>Nike/Voomero v9</td>
<td>Neutral</td>
<td>12+</td>
<td>Left</td>
<td>Yes</td>
<td>RF (L) FF (N)</td>
<td>3 (L)</td>
<td>0 (N)</td>
<td>7 (L)</td>
</tr>
<tr>
<td>10</td>
<td>Nike/Free 6.0</td>
<td>Neutral</td>
<td>12+</td>
<td>Right</td>
<td>No</td>
<td>RF (L) FF (N)</td>
<td>2 (L)</td>
<td>0 (N)</td>
<td>5 (L)</td>
</tr>
</tbody>
</table>

*Means of 3 trials by 4 raters; Thickness and Hardness: the difference between the medial and lateral sides of each shoe; (mm) millimetres; (M) medial asymmetry; (L) lateral asymmetry; (N) neutral/no asymmetry present
7.3.3 Measurements

7.3.3.1 Thickness

A Wayco 6”/Metric/SAE digital calliper (Wayco Equipment LTD, Auckland, New Zealand) was used to measure the thickness of the inner-, mid-, and outer-sole. For this study, measurements were taken to the nearest 1.0 mm consistent with clinicians measurements of wedge and orthotic inserts [235, 236].

7.3.3.2 Hardness

An Asker-C durometer, with an accuracy of 1 unit (Rex Gauge Company Inc., Buffalo Grove, IL., USA) was used to assess the midsole material hardness of each shoe. Converting Asker-C units to millimetres is required to calculate a summation of the thickness and hardness differences between the medial and lateral midsoles [124]. A difference of less than 10-Asker-C units between the medial and lateral midsoles has no discernible difference and is rated neutral or essentially similar hardness. Previous research indicates differences of 10 to 19 Asker-C units to be equivalent to 1 mm of compression on the softer side [124, 230].

7.3.3.3 Measurement location

One expert rater marked each shoe to designate the measurement locations (Figure 6). Lines indicate calliper placement for thickness measurements, and dots indicate durometer placement for hardness measurements.
Thickness measurements were recorded at five medial and lateral locations (three rearfoot and two forefoot) on the mid/outer sole and two locations (rearfoot and forefoot) on the medial and lateral inner sole. Hardness was recorded at two locations (rearfoot and forefoot) on the medial and lateral midsole (Table 7.2). Although variability would exist between raters’ location of measurements, it is assumed that clinicians would mark measurement locations for test-retest repeatability. Therefore, we did not assess the capability of individual raters to correctly place the instruments.
**Table 7.2: Footwear measurement locations**

<table>
<thead>
<tr>
<th>Footwear Measurements</th>
<th>Side of shoe</th>
<th>Location/Abbreviation(s)</th>
<th>Location/Abbreviation(s)</th>
<th>Units of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement 1 (M1): Mid/outer-sole Thickness (mean)</td>
<td>Medial</td>
<td>THM1, THM2, THM3</td>
<td>THM4, THM5</td>
<td>mm</td>
</tr>
<tr>
<td>Measurement 2 (M2): Innersole Thickness</td>
<td>Medial</td>
<td>ITMRF</td>
<td>ITMFF</td>
<td>mm</td>
</tr>
<tr>
<td>Measurement 3 (M3): Mid/outer-sole Thickness (mean)</td>
<td>Lateral</td>
<td>THL1, THL2, THL3</td>
<td>THL4, THL5</td>
<td>mm</td>
</tr>
<tr>
<td>Measurement 4 (M4): Innersole Thickness</td>
<td>Lateral</td>
<td>ITLRF</td>
<td>ITLFF</td>
<td>mm</td>
</tr>
<tr>
<td>Measurement 5 (M5): Midsole Hardness</td>
<td>Medial</td>
<td>HMRF</td>
<td>HMFF</td>
<td>au (hardness)</td>
</tr>
<tr>
<td>Measurement 6 (M6): Midsole Hardness</td>
<td>Lateral</td>
<td>HLRF</td>
<td>HLRF</td>
<td>au (hardness)</td>
</tr>
<tr>
<td>Hardness Difference (HD)*</td>
<td>–</td>
<td>HDRF</td>
<td>HDFF</td>
<td>au (hardness)</td>
</tr>
</tbody>
</table>

*HD is assigned the following values based on the Asker C difference between M5 and M6:

\[
HD = \begin{cases} 
0, & \text{if Asker C difference < 10} \\
\pm 1, & \text{if Asker C difference 10 to 19} \\
\pm 2, & \text{if Asker C difference 20 to 29}
\end{cases}
\]
Total asymmetry score

The TAS is the sum of the thickness and/or hardness differences between medial and lateral aspects of the inner-, mid- and outer-sole in the same shoe. A TAS score of 0 indicates the thickness and hardness are identical or the differences are on opposite sides of the shoe, thus neutralising each other. Medial asymmetry occurs when the measured medial side of the shoe has greater outer-sole wear and/or the midsole is softer or more compressed than the lateral side, and vice versa. The TAS is calculated separately for the rearfoot (TAS<sub>RF</sub>) and the forefoot (TAS<sub>FF</sub>), using the measurement locations in Table 7.2, respectively [165].

TAS is calculated as:

\[
TAS = (M1 + M2) - (M3 + M4) + (HD)
\]

where: M1=medial mid/outer-sole thickness; M2= medial innersole thickness; M3=lateral mid/outer-sole thickness; M4=lateral innersole thickness; HD=mediolateral hardness difference.

7.4 Procedures

Shoe brand and model was recorded to provide descriptive information regarding the types of shoes analysed in this study. Although shoe brand and design type are not the primary aim of this reliability study, we consider this as basic footwear information which all footwear studies should supply. Shoes were classified as neutral or stability by the absence or presence of motion control material or dual-hardness midsole, respectively. The approximate usage of
the shoe was recorded in categories of 0 months (new, never used), 0-6 months, 6-12 months or 12+ months.

### 7.4.1 Trials

Raters independently completed three trials of each thickness and hardness measurement and recorded the scores in separate spreadsheets. TAS were calculated for trials using one, two or three measurements (represented as an average).

### 7.5 Statistical Analysis

Means and standard deviations (SD), were calculated for all footwear measurements and TAS. Intraclass correlation coefficients (ICC) and 95% confidence intervals (CI$_{95\%}$) were calculated for assessing relative reliability between individuals and between novices and experts [237], using IBM SPSS 22.0 (IBM Corp. Armonk, NY, USA). Standard error of measure (SEM) and minimal detectable differences (MDD) were calculated for assessing the absolute reliability of the between-day measurements [238]. When evaluating the differences between novice and expert raters, the means of three measurements were combined for the two expert raters and the two novice raters.

#### 7.5.1 Within-rater reliability (trial-to-trial)

The within-rater reliability of the calliper and durometer measurements at each of the 18 locations were assessed using ICC(2,1) (two-way random effects model). In this case, the rater and subjects have random effects [238]. Three measurements at each location of the 10 shoes were used as input in the model for each rater. Absolute reliability was assessed with the SEM between the three measurements, according to:

$$SEM = SD\sqrt{1 - ICC}$$
The TAS was calculated only once, therefore, within-rater reliability was not assessed for the TAS.

### 7.5.2 Between-rater reliability

Between-rater reliability was assessed for each of the 18 locations, as well as the rearfoot and forefoot TAS. Reliability of single, two and three measurements at each location was assessed using ICC(2,1), ICC(2,2) and ICC(2,3), respectively. The SEM was used to calculate absolute reliability across the trials of all raters.

### 7.5.3 Between-day reliability (test-retest)

The between-day reliability for single, two, and three measurements were assessed using a random effects model ICC(2,1), ICC(2,2) and ICC(2,3), respectively. All 10 shoes, were assessed on two different days, by one novice and one expert rater. Absolute reliability was assessed using the MDD with 95% confidence levels (MDD_{95}) calculated as:

\[ MDD_{95} = 1.96(SEM)\sqrt{2}. \]

MDD\textsubscript{95} provides the minimal value needed to be 95% confident a true change occurs at the patient level in test-retest situations [238].

### 7.5.4 Bland-Altman plots

Bland-Altman plots were constructed to provide the absolute limits of agreement between raters and between day testing. This method allows assessing the agreement between two
measurements, and to identify whether the agreement is affected by the magnitude of measurement [239, 240].

7.5.5 Interpretation of results

Reliability was classified \textit{a priori} as: poor (ICC < 0.40); fair to good (ICC = 0.40–0.75) and excellent (ICC > 0.75) [241]. Sample size was not determined \textit{a-priori} for this study, however, narrow 95% confidence intervals (0.70-0.99) for ICCs assures reliable measurements were achieved.

7.6 Results

7.6.1 Footwear Asymmetry

Asymmetry of each shoe tested is presented in Table 7.1 as averages determined between 4 raters, taking three measurements at each location.

7.6.1.1 Thickness Asymmetry

Eight of 10 shoes presented rearfoot asymmetry due to thickness discrepancies of the inner, mid- and outer-soles (Table 7.1). Of these, four shoes had 1 mm and five shoes had 2-3 mm of thickness asymmetry (medial n=2; lateral n=7). Six shoes had thickness asymmetry at the forefoot; four with 1 mm and two with 2-3 mm (medial n=3; lateral n=3).
7.6.1.2 Hardness Asymmetry

Seven of 10 shoes assessed had less than 10 Asker-C units difference between the medial and lateral midsoles. Three of 10 shoe midsoles had measured hardness differences greater than 10 but less than 20 Asker-C units, equivalent to 1 mm mediolateral compression difference (softer medially n=1 and laterally n=2).

7.6.1.3 Total Asymmetry Score

Eight out of 10 shoes were asymmetric at the rearfoot (medial n =1; lateral n=7) and seven of 10 shoes at the forefoot (medial n=3; lateral n=4). Only one shoe was symmetric at both the rearfoot and the forefoot.

7.6.2 Thickness Measurements

7.6.2.1 Within-rater Reliability

The within-rater reliability (Table 7.3) was excellent with narrow CI95% ranging from (CI95% = 0.50–1.00) for all thickness measurements by novice raters (ICC(2,1) = 0.96–1.00) and expert raters (ICC(2,1) = 0.93–0.99). SEM for digital callipers ranged from 0 mm–1.82 mm and 0–0.60 mm, for novice and expert raters, respectively.
Table 7.3: Within-Rater Reliability for three measurements on one day

<table>
<thead>
<tr>
<th>Location</th>
<th>Novice Rater 1</th>
<th>SEM</th>
<th>Novice Rater 2</th>
<th>SEM</th>
<th>Expert Rater 1</th>
<th>SEM</th>
<th>Expert Rater 2</th>
<th>SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICC (2,1) CI 95%</td>
<td></td>
<td>ICC (2,1) CI 95%</td>
<td></td>
<td>ICC (2,1) CI 95%</td>
<td></td>
<td>ICC (2,1) CI 95%</td>
<td></td>
</tr>
<tr>
<td>THM1</td>
<td>0.99 (0.99-0.99)</td>
<td>0.52</td>
<td>0.99 (0.99-1.00)</td>
<td>0.58</td>
<td>0.99 (0.99-0.99)</td>
<td>0.59</td>
<td>0.99 (0.99-0.99)</td>
<td>0.59</td>
</tr>
<tr>
<td>THM2</td>
<td>0.99 (0.99-0.99)</td>
<td>0.54</td>
<td>0.99 (0.99-1.00)</td>
<td>0.58</td>
<td>0.99 (0.99-1.00)</td>
<td>0.59</td>
<td>0.99 (0.99-1.00)</td>
<td>0.59</td>
</tr>
<tr>
<td>THM3</td>
<td>0.99 (0.97-0.99)</td>
<td>0.59</td>
<td>1.00 (0.99-1.00)</td>
<td>0.00</td>
<td>0.99 (0.99-0.99)</td>
<td>0.58</td>
<td>0.99 (0.99-0.99)</td>
<td>0.58</td>
</tr>
<tr>
<td>THM4</td>
<td>0.99 (0.98-0.99)</td>
<td>0.38</td>
<td>0.99 (0.99-0.99)</td>
<td>0.44</td>
<td>0.99 (0.98-0.99)</td>
<td>0.39</td>
<td>0.99 (0.98-0.99)</td>
<td>0.39</td>
</tr>
<tr>
<td>THM5</td>
<td>0.99 (0.99-0.99)</td>
<td>0.33</td>
<td>0.99 (0.99-1.00)</td>
<td>0.39</td>
<td>0.99 (0.99-0.99)</td>
<td>0.35</td>
<td>0.99 (0.98-0.99)</td>
<td>0.34</td>
</tr>
<tr>
<td>THL1</td>
<td>0.88 (0.70-0.95)</td>
<td>1.82</td>
<td>0.99 (0.99-0.99)</td>
<td>0.51</td>
<td>0.99 (0.98-0.99)</td>
<td>0.49</td>
<td>0.99 (0.98-0.99)</td>
<td>0.50</td>
</tr>
<tr>
<td>THL2</td>
<td>0.99 (0.99-1.00)</td>
<td>0.54</td>
<td>0.99 (0.99-1.00)</td>
<td>0.56</td>
<td>0.99 (0.99-1.00)</td>
<td>0.54</td>
<td>0.99 (0.98-0.99)</td>
<td>0.54</td>
</tr>
<tr>
<td>THL3</td>
<td>0.99 (0.99-0.99)</td>
<td>0.60</td>
<td>0.99 (0.99-1.00)</td>
<td>0.60</td>
<td>0.99 (0.98-0.99)</td>
<td>0.60</td>
<td>0.99 (0.98-0.99)</td>
<td>0.59</td>
</tr>
<tr>
<td>THL4</td>
<td>0.99 (0.98-0.99)</td>
<td>0.42</td>
<td>0.99 (0.99-0.99)</td>
<td>0.43</td>
<td>0.99 (0.98-0.99)</td>
<td>0.39</td>
<td>0.99 (0.98-0.99)</td>
<td>0.38</td>
</tr>
<tr>
<td>THL5</td>
<td>0.99 (0.98-0.99)</td>
<td>0.37</td>
<td>0.99 (0.99-0.99)</td>
<td>0.38</td>
<td>0.99 (0.97-0.99)</td>
<td>0.35</td>
<td>0.98 (0.96-0.99)</td>
<td>0.35</td>
</tr>
<tr>
<td>ITMRF</td>
<td>0.98 (0.95-0.99)</td>
<td>0.21</td>
<td>0.99 (0.95-0.99)</td>
<td>0.18</td>
<td>0.97 (0.91-0.99)</td>
<td>0.22</td>
<td>0.97 (0.91-0.99)</td>
<td>0.22</td>
</tr>
<tr>
<td>IMFF</td>
<td>0.93 (0.82-0.99)</td>
<td>0.23</td>
<td>0.99 (0.96-0.99)</td>
<td>0.10</td>
<td>0.93 (0.79-0.98)</td>
<td>0.19</td>
<td>0.93 (0.79-0.98)</td>
<td>0.19</td>
</tr>
<tr>
<td>ITLRF</td>
<td>0.97 (0.89-0.99)</td>
<td>0.28</td>
<td>0.99 (0.96-0.99)</td>
<td>0.18</td>
<td>0.93 (0.79-0.99)</td>
<td>0.37</td>
<td>0.93 (0.79-0.99)</td>
<td>0.37</td>
</tr>
<tr>
<td>ILFF</td>
<td>0.96 (0.87-0.99)</td>
<td>0.20</td>
<td>0.99 (0.98-0.99)</td>
<td>0.12</td>
<td>0.95 (0.86-0.99)</td>
<td>0.20</td>
<td>0.93 (0.82-0.98)</td>
<td>0.23</td>
</tr>
<tr>
<td>HMRF</td>
<td>0.93 (0.80-0.98)</td>
<td>1.78</td>
<td>0.94 (0.86-0.99)</td>
<td>1.92</td>
<td>0.97 (0.93-0.99)</td>
<td>1.30</td>
<td>0.97 (0.93-0.99)</td>
<td>1.29</td>
</tr>
<tr>
<td>HMFF</td>
<td>0.85 (0.62-0.96)</td>
<td>1.96</td>
<td>0.83 (0.59-0.95)</td>
<td>2.01</td>
<td>0.96 (0.90-0.99)</td>
<td>1.09</td>
<td>0.96 (0.90-0.99)</td>
<td>1.12</td>
</tr>
<tr>
<td>HLRF</td>
<td>0.96 (0.88-0.99)</td>
<td>1.03</td>
<td>0.85 (0.64-0.96)</td>
<td>3.09</td>
<td>0.95 (0.85-0.99)</td>
<td>1.50</td>
<td>0.93 (0.81-0.98)</td>
<td>1.73</td>
</tr>
<tr>
<td>HLF</td>
<td>0.95 (0.86-0.99)</td>
<td>1.86</td>
<td>0.92 (0.80-0.98)</td>
<td>1.77</td>
<td>0.93 (0.82-0.98)</td>
<td>2.24</td>
<td>0.94 (0.83-0.98)</td>
<td>2.08</td>
</tr>
</tbody>
</table>

Th: mid-outer-sole thickness; I: innersole thickness; H: midsole hardness; M: medial; L: Lateral; 1-5: measurement position; RF: rearfoot; FF: forefoot

ICC (2,1): Intraclass correlation coefficient-two way random effects model of single measures

C 95%CI: 95% confidence intervals for ICC score

SEM: Standard error of measure

Measurements of thickness are expressed in (mm); measurements of hardness are expressed in (au) – see Table 7.2
7.6.2.2 Between-rater Reliability

Between-rater reliability (Table 7.4) for all thickness measurements were excellent with ranges, (ICC(2,1) = 0.80–0.99), (ICC(2,2) = 0.97–0.99) and (ICC(2,3) = 0.92–0.99) and moderate to narrow CI95% ranging from 0.50–0.99. Midsole thickness using three measurements resulted in smaller SEM ranging from 0.17 mm–0.40 mm compared to 0.36 mm–0.80 mm and 0.35 mm–0.59 mm for one and two measurements, respectively. Innersole measurements were more precise using two measurements (SEM range 0.10 mm–0.23 mm) than one (SEM range 0.37 mm–0.74 mm) or three measurements (SEM range 0.16 mm–0.31 mm).

7.6.2.3 Between-day Reliability

Between-day reliability was excellent for thickness measurements taken by the novice rater (Table 7.5) (ICC(2,1) range 0.86–0.99, ICC(2,2) range 0.96–1.00, ICC(2,3) range 0.87–1.00) and the expert rater (Table 7.6) (ICC(2,1) range 0.93–1.00, ICC(2,2) range 0.98–1.00, (ICC(2,3) range 1.00–1.00). For both the novice and expert rater, SEM ranged from 0.00 mm–0.60 mm. As expected, MDD deceases as novice and expert raters increase the number of measurements at each location (MDD(2,3) range 2.60 mm–4.70 mm, MDD(2,3) range 1.50 mm–2.88 mm, respectively).
7.6.3 Hardness Measurements

7.6.3.1 Within-rater Reliability

Within-rater reliability (Table 7.3) of hardness measurements were excellent (ICC(2,1) range 0.85–0.97). The SEM ranged from 1.03–3.09 Asker-C units for novice raters and 1.09–2.24 Asker C units for expert raters.

7.6.3.2 Between-rater Reliability

Between-rater reliability (Table 7.4) of hardness measurements ranged from poor to excellent (ICC(2,1) = 0.31–0.74, ICC(2,2)= 0.91–0.98, and ICC(2,3) = 0.85–0.97) with moderate to narrow CI95% (0.45–0.99). Durometer SEM ranged from 3.69–4.91, 1.09–1.74, and 1.38–2.23 Asker C units for one, two and three measurements at each location, respectively.
Table 7.4: Between-Rater Reliability.

<table>
<thead>
<tr>
<th>Measures</th>
<th>One measurement</th>
<th>Two measurements</th>
<th>Three measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Means (SD)</td>
<td>ICC (2,1) (CI 95%)</td>
<td>SEM</td>
</tr>
<tr>
<td>THM1</td>
<td>31.49 (5.68)</td>
<td>0.98 (0.96-0.99)</td>
<td>0.80</td>
</tr>
<tr>
<td>THM2</td>
<td>31.48 (5.74)</td>
<td>0.99 (0.97-0.99)</td>
<td>0.57</td>
</tr>
<tr>
<td>THM3</td>
<td>31.63 (5.94)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.59</td>
</tr>
<tr>
<td>THM4</td>
<td>19.20 (3.95)</td>
<td>0.97 (0.93-0.99)</td>
<td>0.68</td>
</tr>
<tr>
<td>THM5</td>
<td>17.06 (3.58)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.36</td>
</tr>
<tr>
<td>THL1</td>
<td>29.99 (5.04)</td>
<td>0.99 (0.98-0.99)</td>
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</tr>
<tr>
<td>THL2</td>
<td>30.38 (5.45)</td>
<td>0.99 (0.97-0.99)</td>
<td>0.55</td>
</tr>
<tr>
<td>THL3</td>
<td>30.97 (5.98)</td>
<td>0.99 (0.96-0.99)</td>
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</tr>
<tr>
<td>ITMRF</td>
<td>3.84 (1.41)</td>
<td>0.87 (0.61-0.98)</td>
<td>0.51</td>
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<tr>
<td>IMFF</td>
<td>3.45 (0.83)</td>
<td>0.80 (0.53-0.95)</td>
<td>0.37</td>
</tr>
<tr>
<td>ILRF</td>
<td>4.14 (1.69)</td>
<td>0.81 (0.50-0.96)</td>
<td>0.74</td>
</tr>
<tr>
<td>ILFF</td>
<td>3.90 (1.02)</td>
<td>0.83 (0.54-0.96)</td>
<td>0.42</td>
</tr>
<tr>
<td>HMRF</td>
<td>62.10 (8.03)</td>
<td>0.73 (0.49-0.92)</td>
<td>4.17</td>
</tr>
<tr>
<td>HMFF</td>
<td>57.93 (5.91)</td>
<td>0.31 (0.52-0.67)</td>
<td>4.91</td>
</tr>
<tr>
<td>HLRF</td>
<td>57.95 (6.98)</td>
<td>0.72 (0.45-0.91)</td>
<td>3.69</td>
</tr>
<tr>
<td>HLFN</td>
<td>58.65 (7.92)</td>
<td>0.74 (0.79-0.98)</td>
<td>4.04</td>
</tr>
<tr>
<td>TASR</td>
<td>1.30 (1.74)</td>
<td>0.84 (0.66-0.95)</td>
<td>0.70</td>
</tr>
<tr>
<td>TASF</td>
<td>-0.06 (1.35)</td>
<td>0.83 (0.63-0.95)</td>
<td>0.56</td>
</tr>
</tbody>
</table>

TH: mid-outer sole thickness; I: inner sole thickness; H: midsole hardness; M: medial; L: lateral; 1-5: measurement position; RF: rearfoot; FF: forefoot
ICC (2,1): Intraclass correlation coefficient-two way random effects model of single measures; ICC (2,2): Intraclass correlation coefficient-two way random effects model of two measures; ICC (2,3): Intraclass correlation coefficient-two way random effects model of three measures CI95%: 95% confidence intervals for ICC score; SEM: Standard error of measure
Measurements of thickness are expressed in (mm); measurements of hardness are expressed in (au) - see Table 7.
7.6.3.3 Between-day Reliability

Between-day reliability for novice raters (Table 7.5) improved from good reliability (ICC(2,1) range 0.67–0.89; with wide to moderate CI 95% -0.24–0.96) to excellent reliability (ICC(2,2) range 0.90–0.96 and ICC(2,3) range 0.92–0.98; with narrow CI95% 0.73–0.99). The expert rater had excellent between-day reliability (Table 7.6) (ICC(2,1) range 0.96–0.97, ICC(2,2) range 0.99–0.99, ICC(2,3) range 0.98–0.99) with narrow CI95% (0.90–0.99). The novice rater had small SEM ranging from 0.94–1.70 Asker-C units and MDD 2.60–4.70 Asker-C units, when hardness was measured three times at each location. The expert rater SEM and MDD was smallest when two hardness measurements were taken at each location, resulting in SEM ranging from 0.55–0.82 Asker C units and MDD 1.53–2.26 Asker-C units.

7.6.4 Total Asymmetry Scores

7.6.4.1 Between-rater Reliability

Between-rater reliability (Table 7.4) of the TAS was excellent (ICC(2,1) range 0.83–0.84, ICC(2,2) range 0.90–0.96, ICC(2,3) range 0.94–0.98) with narrow CI95% (0.63–0.99).

7.6.4.2 Between-day Reliability

Between-day reliability (novice: Table 7.5; expert: Table 7.6) was consistent across all measurements for a novice (ICC(2,1) range 0.94–0.897, ICC(2,2) range 0.95–0.98, ICC(2,3) range 0.95–0.98) and expert raters (ICC(2,1) range 0.96–1.00), (ICC(2,2) range 0.97–1.00), (ICC(2,3) range 1.00–1.00). The SEM for the TAS was less than 0.50 mm (ranging from 0 mm–
0.37 mm) by novice and expert raters. Novice and expert raters can be 95% confident a true change beyond error occurs when between-day measurements are greater than 1.00 mm.

### 7.6.5 Bland-Altman plots

Bland-Altman plots showed that the differences between-raters for most measurements were random (Appendix 14). However, slight trends were observed for measurements of lateral midsole thickness at all five measurement locations. As thickness of the midsoles increases, novice raters report higher caliper measurements than the expert raters. In contrast, as midsole hardness increases, novice rater tend to report lower hardness measurements than expert raters. Most between-day measurements for both novice and expert raters showed non-systematic differences. The novice rater reported decreased measurements of the medial midsole thickness on the second assessment day. Additionally, the TASRF scores were lower on the second assessment day for the novice rater. Bland-Altman plots are presented in Appendix 14 for measurements between-raters and between-day for novice and expert raters.
<table>
<thead>
<tr>
<th>Location</th>
<th>Mean (SD)</th>
<th>ICC (2,1) (CI 95%)</th>
<th>SEM</th>
<th>MDD</th>
<th>Means (SD)</th>
<th>ICC (2,2) (CI95%)</th>
<th>SEM</th>
<th>MDD</th>
<th>Means (SD)</th>
<th>ICC (2,3) (CI95%)</th>
<th>SEM</th>
<th>MDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>THM1</td>
<td>31.84 (5.26)</td>
<td>0.99 (0.96-0.99)</td>
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<td>1.46</td>
<td>31.93 (5.20)</td>
<td>0.99 (0.99-0.99)</td>
<td>0.52</td>
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<td>31.97 (5.17)</td>
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<td>0.79</td>
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<td>THM2</td>
<td>31.88 (5.42)</td>
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<td>0.54</td>
<td>1.50</td>
<td>31.93 (5.37)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.54</td>
<td>1.49</td>
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<tr>
<td>THM3</td>
<td>32.06 (6.00)</td>
<td>0.99 (0.98-1.00)</td>
<td>0.60</td>
<td>1.66</td>
<td>32.08 (5.91)</td>
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<td>0.00</td>
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<tr>
<td>THM4</td>
<td>19.38 (3.99)</td>
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<td>1.11</td>
<td>19.32 (3.95)</td>
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<td>THM5</td>
<td>17.26 (3.46)</td>
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<td>1.36</td>
<td>17.25 (3.42)</td>
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<td>0.34</td>
<td>0.95</td>
<td>17.27 (3.40)</td>
<td>0.99 (0.99-0.99)</td>
<td>0.22</td>
<td>0.60</td>
</tr>
<tr>
<td>TML1</td>
<td>30.08 (5.03)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.50</td>
<td>1.40</td>
<td>30.17 (4.94)</td>
<td>0.99 (0.99-0.99)</td>
<td>0.49</td>
<td>1.37</td>
<td>30.38 (5.05)</td>
<td>0.98 (0.99-0.99)</td>
<td>0.66</td>
<td>1.82</td>
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<td>TML2</td>
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<td>0.55</td>
<td>1.52</td>
<td>30.74 (5.36)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.54</td>
<td>1.49</td>
<td>30.73 (5.38)</td>
<td>0.99 (0.99-1.00)</td>
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<td>0.47</td>
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<td>1.66</td>
<td>31.39 (5.93)</td>
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<td>1.65</td>
<td>31.15 (5.88)</td>
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</tr>
<tr>
<td>TML5</td>
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<td>0.38</td>
<td>1.04</td>
<td>17.33 (3.74)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.37</td>
<td>1.04</td>
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<td>0.29</td>
<td>0.79</td>
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<tr>
<td>ITMRF</td>
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<td>0.91 (0.76-0.98)</td>
<td>0.43</td>
<td>1.19</td>
<td>3.89 (1.45)</td>
<td>0.98 (0.93-0.99)</td>
<td>0.21</td>
<td>0.57</td>
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<td>0.92 (0.93-0.99)</td>
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<td>1.18</td>
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<tr>
<td>HMFF</td>
<td>3.72 (0.84)</td>
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<td>0.19</td>
<td>0.47</td>
<td>3.70 (0.82)</td>
<td>0.98 (0.97-0.99)</td>
<td>0.08</td>
<td>0.23</td>
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<td>0.96 (0.97-0.99)</td>
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<td>ITLLR</td>
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<td>0.86 (0.65-0.97)</td>
<td>0.59</td>
<td>1.62</td>
<td>3.89 (1.48)</td>
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<td>0.19</td>
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<td>0.28</td>
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<td>HRMS</td>
<td>64.65 (6.78)</td>
<td>0.89 (0.69-0.96)</td>
<td>2.25</td>
<td>6.23</td>
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<td>60.10 (4.82)</td>
<td>0.80 (0.59-0.94)</td>
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<td>1.18</td>
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<td>1.50</td>
<td>4.17</td>
<td>60.95 (4.62)</td>
<td>0.92 (0.81-0.98)</td>
<td>1.31</td>
<td>3.62</td>
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<td>3.58</td>
<td>9.93</td>
<td>60.60 (6.48)</td>
<td>0.91 (0.77-0.96)</td>
<td>1.94</td>
<td>5.39</td>
<td>60.52 (6.92)</td>
<td>0.94 (0.87-0.98)</td>
<td>1.70</td>
<td>4.70</td>
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<td>TARS</td>
<td>1.48 (1.52)</td>
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<td>0.98 (0.90-0.99)</td>
<td>0.22</td>
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<td>1.03</td>
<td>0.09 (1.52)</td>
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<td>0.34</td>
<td>0.94</td>
<td>0.09 (1.51)</td>
<td>0.95 (0.81-0.99)</td>
<td>0.34</td>
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</table>

**Table 7.5: Between-Day Reliability (novice)**

**ICC (2,1):** Intraclass correlation coefficient-two way random effects model of single measures; **ICC (2,2):** Intraclass correlation coefficient-two way random effects model of two measures; **ICC (2,3):** Intraclass correlation coefficient-two way random effects model of three measures; **CI95%:** 95% confidence intervals for ICC score; **SEM:** Standard error of measure; **MDD:** Minimal Detectable Difference for 95% confidence of true measurement differences.
Measurements of thickness are expressed in (mm); measurements of hardness are expressed in (au) - see Table 7.2
### Table 7.6: Between-Day Reliability (expert)

<table>
<thead>
<tr>
<th>Location</th>
<th>Mean (SD)</th>
<th>ICC (2,1) (CI 95%)</th>
<th>SEM</th>
<th>MDD</th>
<th>Means (SD)</th>
<th>ICC (2,2) (CI95%)</th>
<th>SEM</th>
<th>MDD</th>
<th>Means (SD)</th>
<th>ICC (2,3) (CI95%)</th>
<th>SEM</th>
<th>MDD</th>
</tr>
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<td></td>
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<td>%1</td>
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<tr>
<td></td>
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<td>Expert One Measurement</td>
<td></td>
<td></td>
<td>Expert Two Measurements</td>
<td></td>
<td></td>
<td>Expert Three Measurements</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>THM1</td>
<td>31.40 (5.95)</td>
<td>0.99 (0.99-0.99)</td>
<td>0.60</td>
<td>1.65</td>
<td>31.28 (5.85)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.59</td>
<td>1.62</td>
<td>31.32 (5.81)</td>
<td>1.00 (0.99-1.00)</td>
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<td>31.35 (5.95)</td>
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<td>0.59</td>
<td>1.65</td>
<td>31.30 (5.84)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.58</td>
<td>1.62</td>
<td>31.33 (5.80)</td>
<td>1.00 (0.99-1.00)</td>
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<td>0.58</td>
<td>1.61</td>
<td>31.45 (5.76)</td>
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<td>1.60</td>
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<td>THM4</td>
<td>19.30 (3.84)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.38</td>
<td>1.06</td>
<td>19.30 (3.86)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.39</td>
<td>1.07</td>
<td>19.30 (3.82)</td>
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<td>THM5</td>
<td>16.90 (3.74)</td>
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<td>0.37</td>
<td>1.04</td>
<td>16.95 (3.54)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.35</td>
<td>0.98</td>
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<td>1.00 (0.99-1.00)</td>
<td>0.00</td>
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</tr>
<tr>
<td>THL1</td>
<td>29.90 (5.10)</td>
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<td>0.51</td>
<td>1.41</td>
<td>29.70 (4.90)</td>
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<td>0.49</td>
<td>1.36</td>
<td>29.67 (4.88)</td>
<td>1.00 (0.99-1.00)</td>
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<td>THL2</td>
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<td>0.55</td>
<td>1.52</td>
<td>30.10 (5.42)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.54</td>
<td>1.50</td>
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<td>THL3</td>
<td>30.60 (6.02)</td>
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<td>0.60</td>
<td>1.67</td>
<td>30.70 (5.96)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.60</td>
<td>1.65</td>
<td>30.73 (5.94)</td>
<td>1.00 (0.99-1.00)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
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<td>THL4</td>
<td>18.40 (3.90)</td>
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<td>0.39</td>
<td>1.08</td>
<td>18.25 (3.80)</td>
<td>0.99 (0.99-1.00)</td>
<td>0.38</td>
<td>1.05</td>
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<td>THL5</td>
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<td>0.33</td>
<td>0.92</td>
<td>17.05 (3.46)</td>
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<td>0.35</td>
<td>0.96</td>
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<td>0.00</td>
<td>3.57 (1.20)</td>
<td>1.00 (1.00-1.00)</td>
<td>0.00</td>
<td>0.00</td>
<td>3.52 (1.23)</td>
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<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>IMFF</td>
<td>3.25 (0.68)</td>
<td>0.93 (0.82-0.98)</td>
<td>0.18</td>
<td>0.50</td>
<td>3.19 (0.74)</td>
<td>0.98 (0.94-0.99)</td>
<td>0.10</td>
<td>0.29</td>
<td>3.21 (0.71)</td>
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<td>0.95 (0.86-0.99)</td>
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<td>0.94</td>
<td>3.71 (1.36)</td>
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<td>0.19</td>
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<td>0.55</td>
<td>3.56 (0.88)</td>
<td>0.98 (0.96-0.99)</td>
<td>0.12</td>
<td>0.34</td>
<td>3.58 (0.87)</td>
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<td>0.97 (0.92-0.99)</td>
<td>1.31</td>
<td>3.62</td>
<td>62.75 (7.31)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.73</td>
<td>2.03</td>
<td>62.68 (7.35)</td>
<td>0.98 (0.97-0.99)</td>
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<td>2.88</td>
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<td>1.09</td>
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<td>0.55</td>
<td>1.53</td>
<td>59.30 (5.40)</td>
<td>0.99 (0.93-0.99)</td>
<td>0.54</td>
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<td>1.48</td>
<td>4.10</td>
<td>57.45 (6.68)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.67</td>
<td>1.85</td>
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<td>1.83</td>
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<td>HLF</td>
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<td>1.48</td>
<td>4.10</td>
<td>58.65 (8.17)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.82</td>
<td>2.26</td>
<td>58.20 (8.22)</td>
<td>0.99 (0.98-0.99)</td>
<td>0.82</td>
<td>2.28</td>
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<td>0.00</td>
<td>1.61 (1.81)</td>
<td>1.00 (1.00-1.00)</td>
<td>0.00</td>
<td>0.00</td>
<td>1.61 (1.84)</td>
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<td>0.22 (0.88)</td>
<td>0.97 (0.89-0.98)</td>
<td>0.15</td>
<td>0.42</td>
<td>0.31 (1.02)</td>
<td>1.00 (1.00-1.00)</td>
<td>0.00</td>
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</tr>
</tbody>
</table>

**ICC (2,1):** Intraclass correlation coefficient-two way random effects model of single measures; **ICC (2,2):** Intraclass correlation coefficient-two way random effects model of two measures; **ICC (2,3):** Intraclass correlation coefficient-two way random effects model of three measures

**CI95%:** 95% confidence intervals for ICC score

**SEM:** Standard error of measure; **MDD:** Minimal Detectable Difference

Measurements of thickness are expressed in (mm); measurements of hardness are expressed in (au) - see Table 7.2
7.7 Discussion

The footwear TAS has excellent reliability for measuring the mediolateral asymmetry present in running footwear. Novice and expert raters can determine the rearfoot and forefoot TAS within 0.50 mm of the true asymmetry scores using one, two or three measurements of thickness and hardness at each measurement location.

7.7.1 Thickness and hardness measurements

The within-rater and between-rater reliability of thickness and hardness measurements can be affected by rater experience, variations between trials and measurement error associated with the digital callipers and durometer. Our study reported an overall excellent reliability for novice and expert raters using the digital callipers and an Asker-C durometer. Previous studies have used a metric ruler to measure midsole thickness [23, 133]. We are unaware of any studies that assessed the reliability of digital callipers to measure footwear mid/outer or inner-sole thickness. The within-rater reliability for novice and expert raters using an Asker-C durometer for measurements of midsole hardness were very high, and compare favourably to Barton et al. (2009) [23] (within-rater reliability ICC range 0.93–0.97). Barton et al. (2009). [23], used a Shore A durometer which has a slightly stronger spring than the Asker-C durometer and is used for testing the hardness of soft plastics and general rubber [23]. Our results suggest both novice and expert raters obtain consistent measurements with an Asker-C durometer (SEM < 3.00 Asker-C units).

Innersole measurements were more reliable with two trials compared to three trials. However, the differences between trials was small and could be attributed to some variability of the measurement. Reliability of the innersole thickness measurements influenced, firstly,
by the relative thickness, which provides greater relative variability with repeated measurements. Furthermore, the innersole material is much softer than the mid- and outersoles, making it more difficult to accurately measure using the Vernier calliper.

### 7.7.2 Clinical and Research Applications

The digital calliper and durometer are portable tools that can be used in a variety of clinical and research settings to assess footwear TAS. Clinicians and researchers can reliably assess footwear TAS to monitor asymmetry changes over time and improve understanding of symptoms or pathologies related to asymmetric footwear. Furthermore, monitoring footwear asymmetry will help identify thresholds where certain asymmetric patterns may be indicative of injury. This would allow effective treatment and prevention strategies to be developed.

Biomechanical analyses of running may also be enhanced by considering footwear asymmetry scores and may improve understanding of the effects of footwear on discrete movement variables. With effective monitoring, these footwear asymmetry scores may identify footwear patterns that lead to specific symptom presentations or injuries. Prospective studies of the TAS are needed to establish associations between injury outcomes and asymmetric footwear, caused by shoe design and/or degradation.

### 7.7.3 Limitations

Marks were drawn on the shoes to indicate optimal placement for calliper and durometer measurements in the research setting. Thus, the ability for individual raters to identify the locations of each measurement was not determined. The reliability focused on the actual measurement using the durometer and the callipers. The rearfoot and forefoot measurements were averaged to calculate the respective TAS. In clinical and research settings,
the marks would ideally be drawn during the initial assessment and used for follow-up measurements.

As there is currently not specific standard criteria to suggest the life of a shoe, the inclusion of categorial shoe age could be misinterpreted. Many variable impact the ‘life’ of a shoe including the runners mass, strike pattern, the ground-contact time, the shoe material (including density and type of material), and the terrain. Additionally, many footwear materials are biodegradable, so even if the footwear had only been ‘used’ for 3 months, it is unknown how long the shoes were held in the store, or under what types of conditions that may have initiated the decomposition of the shoes. This is an area that is need of improvement in the literature. A question worth asking is: should footwear come with a ‘sell-by date’?

Four shoes were designed with a fashion band at the upper portion of the midsole which were not included in the thickness measurements, as it is not compressed during shoe use. In some cases the durometer placement was affected by midsoles designed with uneven surfaces. Therefore the durometer mark was moved slightly either anteriorly or posteriorly to a smoother surface where the indenter could be compressed completely. Durometers with different head surface areas allow measurement of smaller surfaces and could be assessed in future studies.

Some statistical analyses (i.e. linear mixed models) of the TAS may be complicated by the presence of two scores (rearfoot and forefoot). Thus, a sum of the absolute values of rearfoot and forefoot asymmetry may be suitable to provide the magnitude of asymmetry, and the TAS can be used in a sub-analyses of the direction (medial or lateral) and location (rearfoot or forefoot) of asymmetry.
7.8 Conclusions

The TAS is a reliable footwear assessment tool for determining the mediolateral asymmetry at the rearfoot and forefoot of running shoes. Novice and expert raters can reliably measure the thickness and hardness of the inner and mid/outer-sole using two or three measurements at each location. Novice and expert raters can be 95% confident a true change occurs when TAS differ more than 1 mm in test-retest situations. The potential association between asymmetric footwear and overuse running-related injuries requires clinical monitoring and prospective observational research.

7.9 In the next chapter

Findings reported in the Chapter regarding the psychometric properties of the footwear total asymmetry score tool (TAS) informed how to interpret data gathered from the feasibility study that is reported in the next Chapter. Chapter 8 will determine the feasibility of an observational study which uses the TAS to assess footwear among novice runners training for a half-marathon.
8 CHAPTER 8: FOOTWEAR ASYMMETRY ON OVERUSE

RUNNING-RELATED INJURIES: A FEASIBILITY STUDY

8.1 Chapter Overview

Following the reliability of the TAS tool described in the previous Chapter, the current Chapter presents the main research study of this PhD project. It addresses the final research question: *Is it feasible to conduct an experimental study to determine association between footwear asymmetry and RRI among runners?* This Chapter contributes to the footwear micro-system by presenting a novel perspective of assessing the effects of footwear asymmetries on RRI.

8.2 Background

Running-related injuries (RRI) are well documented among runners, with prevalence rates ranging from 19 to 92% and incidence rates of up to 33 injuries per 1000 hours of training [16, 17, 149]. Footwear is among the most commonly studied modifiable risk factor [46, 68, 227]. Indeed, due to the plethora of footwear styles and characteristics, many methodological inconsistencies and conflicting results exist among current studies (Chapter 2). From a psychosocial perspective, runners believe that footwear is a key component to prevent injury [73, 199]. They also utilise multiple sources (i.e. past experiences, anecdotal evidence from other runners, and specific measurements) to make well-informed footwear purchases (Chapter 5). Clinicians are inconsistent when evaluating footwear and give preference to biomechanical gait assessments in the management of patients with RRI (Chapter 6). This could be due to a lack of evidence-based support regarding the effectiveness of footwear in preventing running-related injury (Chapter 4).
Footwear assessment tools have been developed as an attempt to overcome some of the challenges with footwear in clinical practice and research (Chapter 2). Among these, the Total Asymmetry Score (TAS) tool is a reliable assessment determining the mediolateral differences of sole thickness and hardness [130]. Current use of the TAS tool has shown footwear with as little as 1mm of asymmetry (by either design or degradation), to impair neuromuscular performance and postural stability during dynamic single-legged tasks [124, 128]. Additionally, footwear with rearfoot lateral bias alters the plantar pressure profiles of healthy active adults and those with previous lateral ankle sprains, and induces adaptive strategies while walking [170]. Given these effects and the task requirements for running (i.e. single legged balance, dynamic movement and foot-ground contact), it is plausible that asymmetric footwear may be a risk factor for RRI.

The direction of current injury research suggests traditional epidemiological approaches need to embrace a systems-based perspective to progress RRI prevention strategies [83]. This involves establishing control and feedback mechanisms to inform relevant actors and organisations within the running-injury system [81]. Indeed, the gap between the theory of systems-based research and practice in real-world settings must be addressed by developing measures that are feasible and practical to the end-users (clinicians, researchers, coaches and athletes) [105]. The use of the TAS tool in current published literature is limited to controlled laboratory environments [128, 165, 170]. Additionally, the relationships between asymmetric footwear and RRI has not been established. Given these issues, the current study assessed the feasibility of conducting a prospective cohort study, for assessing the association between footwear asymmetry and RRI. Information from this study can be used to inform the design of future studies assessing RRI within the footwear micro-system.
8.3 Methods

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for cross sectional studies was used to report this study (Appendix 15) [242]. The STROBE statement provides guidelines for reporting clear and robust information throughout all sections of a research article [242].

8.3.1 Study design

This is a prospective, repeated measures study (baseline, week 3, week 6, week 9 and week 12), designed to explore the feasibility of assessing the association between footwear asymmetry and RRI. Ethical approval was obtained from the University of Otago Human Ethics Committee (Appendix 16) and Māori (New Zealand indigenous people) consultation was undertaken (Appendix 17). Prior to baseline data collection, all participants provided written informed consent.

8.3.2 Participants

8.3.2.1 Sample size estimation

To determine the sample size for the present study, we consulted with a biostatistician. In order to estimate standard deviations and correlation coefficients between variables, and the sample size for the full trial, a minimum of 30 participants is required for this feasibility study. Considering a drop-out rate of 20%, we aimed to recruit a total of 38 novice runners. Thirty-eight participants will allow us to conduct a linear mixed-effect model analysis with the three most relevant independent variables (for details, please refer to statistical analysis section 8.3.5).
8.3.2.2 Eligibility

Recruitment advertisements (Appendix 18) were displayed at local running clubs, specialty running stores, gyms/fitness facilities, as well as social media (Facebook and Twitter) pages. Eligible participants were aged between 18 and 55 years old, could run at least 20 minutes continuously, could provide their own pair of self-selected running shoes and were registered (or willing to register) for the 2017 Cadbury Half Marathon in Dunedin, New Zealand. Runners were excluded if they had previous lower-limb injuries that required surgery, were training more than five days per week or had previously run more than one half-marathon or a longer distance race.

8.3.3 Setting

The present study recruited novice runners from Dunedin, New Zealand to follow a standardised half-marathon training program (Appendix 19) that began on June 19, 2017 and finished on September 10, 2017 at the completion of the 2017 Cadbury Half-Marathon. The recruitment period was between April 4, 2017 and June 15, 2017. Individuals who were interested in the study were directed to the study website (www.otago.ac.nz/running-study) where they could access the information sheet (Appendix 20) and an eligibility questionnaire. The questionnaire was designed with progression logic which filtered eligible participants to a follow-up health questionnaire where further inclusion criteria were assessed. Eligible participants were admitted into the database where they were assigned a participant identification number and contacted by the research team via email to schedule baseline assessments. Ineligible participants were prompted and exited the survey and a member of
the research team followed-up with excluded participants to ensure they understood the reasons for exclusion.

All physical data (baseline testing and follow-up footwear TAS assessments) were collected at the School of Physiotherapy on the University of Otago campus. Research Electronic Data Capture (REDCap) software [243] was used to collect all survey data (eligibility, weekly training log and pain reports, and footwear comfort). The REDCap platform was chosen because data are stored locally rather than through cloud-based servers, ensuring the safety and security of sensitive participant data [243]. REDCap also features automatic email scheduling of weekly surveys and reminder notifications which are sent to participants with incomplete or missing responses, ensuring data completeness for the study.

8.3.3.1 Baseline assessments

At baseline, the primary researcher recorded demographic data including: basic anthropometric measurements, Foot Posture Index [244], and gait assessment. Each runners strike pattern was categorised as: rearfoot, midfoot or forefoot [72]. This assessment was done using a treadmill and video analysis (Hudl Technique software, Lincoln, Nebraska, USA) as described by [245]. The REDCap app was downloaded to an iPad (version 3, Apple Inc, 2016), in which the primary researcher could access each participant’s file using their pre-assigned participant identification number, and manually enter the participant’s baseline data in real-time. The iPad was connected to the University of Otago secure wireless network, and all data were stored and secured on the local server.
8.3.3.1 Footwear

The TAS scores [129] of each participant’s footwear were measured using a digital calliper (Ingco HDCD01150, Stainless steel150mm/6”, Shanghai) and a Type E durometer (Teclock, GS-721G, Hong Kong). TAS measurements were entered into the participants REDCap file. Participants assessed their baseline comfort scores with a modified-version of the footwear comfort tool [140] which was developed for use in REDCap. The visual analogue scales were modified to include sliders rather than radio buttons (Figure 7). This allowed footwear comfort to be recorded as a numeric scale rather than categorical data. Since participants self-selected their shoes, the shoe age was recorded categorically as: 0-6 months; 6-12 months, and 12+ months of usage.

![Figure 7: Modified comfort tool using sliders, implement in REDCap](image)

8.3.3.2 Pain

Baseline pain was recorded in REDCap using the Oslo Sports Trauma Research Centre (OSTRC) overuse injury questionnaire [38]. The questionnaire contains four items that focus on capturing pain levels and the effects of pain on sport participation and performance [38]. The term ‘injury’ is replaced with ‘problem’ and is described as any pain, ache, stiffness, swelling, instability/giving way, locking or other complaints related to any selected anatomical area. This eliminates bias or methodological errors associated with defining and assessing specific injuries. The OSTRC tool identifies more than 10 times as many cases when compared to
standard methods of time-loss injuries [38]. Participants indicated all areas of pain using a Collaborative Health Outcomes Information Registry (CHOIR) body map (Figure 8). Participants then indicated and completed the rest of the OSTRC questionnaire based on the area of most concern. This area was referred to as the ‘pain side’ and was used to correlate the footwear TAS and comfort footwear scores to the area of pain. Similarly, the opposite side that was not indicated with an area of most concern was considered the ‘non-pain side’.

Figure 8: CHOIR Body map

8.3.3.2 Follow-up

Follow-up assessment took place at week 3 (July 3-7); week 6 (July 24-28), week 9 (August 14-18) and week 12 (September 4-8). During these time points the following were assessed: footwear TAS scores, footwear comfort scores and pain severity and location.
8.3.3.2.1 Training and pain log

Each Sunday participants received an email with a link to a survey where they could verify the training sessions they completed and report any running-related pain. The survey link was matched to their profile in REDCap and was automatically generated. If participants failed to submit the training and pain log, reminder emails were sent every 24-hours for three consecutive days. Participants reported weekly training and pain logs to limit recall bias during the assessment weeks.

8.3.3.2.2 Footwear assessments

The TAS and comfort scores of participants’ footwear were assessed at baseline and four follow-up time points: week 3 (July 3-7), week 6 (July 24-28), week 9 (August 14-18) and week 12 (September 4-8). These measurement intervals were chosen based on previous literature indicating that significant levels of shoe degradation occur around 160 km [113]. For the present study, the 160 km distance was achieved during week 7 of training, although shoe-use before the study may result in participant’s footwear reaching 160 km of use before week 7. Additionally, the perceived comfort of footwear can be affected by changes in footwear properties [246, 247].

8.3.3.2.3 Exit survey

Participants who completed the entire study were sent a satisfaction survey after they submitted the final OSTRC pain questionnaire. Data from the survey were used to inform the satisfaction component of the feasibility study. Participants also indicated their thoughts on the TAS tool. This provided a qualitative component to this study, adding further depth to the discussion of the uses for the TAS tool in the running-injury system.
8.3.3.3 12-week training program

Following baseline testing, participants received a 12-week standardised training program leading up to the Cadbury Half Marathon on September 10, 2017. The standardised training program included safe increases to training load using a “10% rule” [248, 249]. Participants completed four training sessions per week and 2-3 days of active rest/cross training and recovery [250]. Rapid increases to training load—intensity, volume or duration—have been associated with overuse injuries as muscles, tendons and/or bones have not yet adapted to training (typical in novice runners) and are overloaded [39, 251]. A systematic review found a U-shaped trend in the frequency of training, indicating that risk of injury is higher in runners who train only once per week and in those who train 6-7 times per week [252]. Due to the program extending through the winter months, participants could choose the terrain (i.e. treadmill, indoor running track, or outdoors) and time of day to complete the training. These factors were not recorded or included in any analyses.

8.3.4 Variables

8.3.4.1 Primary Outcomes: Feasibility

Participant recruitment were assessed by the number of eligible participants who consented to participant in this study.

Drop-out/retention rates were quantified as the number of participants who attended the footwear assessment sessions and who completed the Cadbury Half-Marathon.
Adherence was assessed by the number of training sessions completed, number of footwear assessment sessions attended; and online training logs submitted throughout the 12-week training program.

Participant satisfaction was assessed at the 12-week follow-up assessment using a 5-point Likert scale that covered the following components of the study: overall study procedures, the time taken for footwear assessments, compliance and enjoyment of the training program, use of the online training log/questionnaires, and satisfaction of half-marathon results.

8.3.4.2 Secondary Outcomes: Footwear and Pain

Preliminary analysis was carried out to evaluate the relationships between footwear TAS and comfort scores on lower-limb pain at five time points (baseline, week 3, week 6, week 9 and week 12). For that preliminary analysis, the following were used as secondary outcome measures: footwear TAS, comfort and lower-limb pain severity.

Footwear TAS is expressed in millimetres and was assessed using a calliper and durometer to measure the inner and mid/outer-sole height and density, respectively. This method has previously been shown reliable (Intra-rater ICC ranging from 0.97 to 0.99; SEM=0.2mm; and inter-rater ICC ranging from 0.93 to 0.96; SEM =0.3mm) (Chapter 5).

Comfort was assessed using the Footwear Comfort Assessment tool [140], and expressed in arbitrary comfort points (ranging from 1 to 100).

Lower limb pain severity was self-reported using the Oslo Sports Trauma Research Centre (OSTRC) tool [38]. The OSTRC pain scores were used as the dependent variable and were described categorically as no pain, mild pain, moderate pain or severe pain.
8.3.5 Statistical analysis

Statistical Package for the Social Sciences (SPSS, Version 25) (IBM corp., 1989, 2015) was used to carry out preliminary statistical analyses. Descriptive statistics were reported as means and standard deviations for continuous variables and counts and percentages for categorical data.

8.3.5.1 Feasibility statistical analysis

A fully-powered prospective study will be considered feasible based on the following a priori criteria: successful recruitment of at least 38 participants which account for a 20% drop-out rate to allow preliminary statistical analyses (see section 8.3.5.2); adherence to the training program of 90% for runners who report zero injuries. These criteria suggest participants followed the training program and extraneous variables related to training errors (i.e. overtraining) can be controlled through a standardised training program and is consistent with adherence rates in a pilot RCT [47]; a 75% participant satisfaction of the study procedures, training program and race results. For the purpose of this study, feasibility was categorically assessed as poor (<70%), moderate (70-89%) and high (>90%).

8.3.5.2 Preliminary statistical analysis

If numbers allow (i.e. sample size n=30), preliminary statistics was conducted using a linear mixed-model to explore the effects of TAS scores (absolute, rearfoot and forefoot) on the participant’s self-reported pain scores. Here, the primary analysis would evaluate the differences of the total TAS scores (summation of the rearfoot and forefoot absolute values) for the injured and non-injured sides on the presence of pain over the 12-week training
program. The advantage of a linear mixed-model is that it can handle missing data from participants who dropped out of the study [253].

In case of sample size being smaller than the minimum required (i.e. n=30) an alternative analysis was planned. In this case, visual inspection of a scatter plot was included for assessing the possible association between footwear TAS and running-related pain. The association between each factor (participants’ age, BMI, FPI, gait pattern, running experience, previous injury and shoe age) and running-related pain was assessed using a linear mixed-model.

Before exploring the association between factors and running-related pain, the association between time factor and pain was assessed. Participants were entered into the model as random-effects to handle the within-participant repeated measures over-time. Footwear measurements were entered as fixed effects and were continuous variables (TAS measurements presented in millimetres as whole numbers; comfort scores from VAS 1-100).

8.4 Results

8.4.1 Participants

Eighty survey respondents expressed interest in the study, representing approximately .07% the population between the ages of 20-55 years, in Dunedin, New Zealand (111,036 per 2013 census). Of the survey respondents, 46 were eligible to participate, however 17 failed to submit the follow-up survey and one participant did not schedule baseline assessment (Figure 9).
Therefore, 27 participants were included in the study (Table 8.1). All included participants were women (mean age: 29 SD ± 9 years; BMI 23.4 SD ±2.7 kg/m²; FPI 3.5 SD ±2.8 arbitrary units), with running experience mean range: 6-12 months, had never run a half-marathon or longer distance and 18/25 (72%) reported having a previous injury to the lower limb that caused reduction or cessation of activity. The strike patterns for the included participants...
were categorised as: rearfoot (18/25), midfoot (5/25), and forefoot (2/25) and the mean self-selected treadmill speed during gait analysis was 8.0 km/h, SD ±1.8 km/h.

Table 8.1: Participant demographics

<table>
<thead>
<tr>
<th></th>
<th>Total (n=27)</th>
<th>Completed (n=15)</th>
<th>Drop-outs (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (SD)</td>
<td>29.5 (9.3)</td>
<td>29.4 (9.5)</td>
<td>29.0 (9.9)</td>
</tr>
<tr>
<td>BMI, kg/m² (SD)</td>
<td>23.4 (2.7)</td>
<td>23.5 (2.7)</td>
<td>23.7 (2.7)</td>
</tr>
<tr>
<td>Previous Injury</td>
<td>19 (70%)</td>
<td>11 (73%)</td>
<td>8 (67%)</td>
</tr>
<tr>
<td>Running Experience (&gt;12 months)</td>
<td>8 (30%)</td>
<td>4 (27%)</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>Foot Posture Index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left (SD)</td>
<td>3.5 (2.8)</td>
<td>2.7 (2.0)</td>
<td>5.1 (3.1)</td>
</tr>
<tr>
<td>Right (SD)</td>
<td>3.4 (3.0)</td>
<td>2.4 (2.2)</td>
<td>5.2 (3.2)</td>
</tr>
<tr>
<td>Gait Pattern</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rearfoot</td>
<td>20</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Midfoot</td>
<td>5</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Forefoot</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Treadmill Speed km/h (SD)</td>
<td>8.0 (1.8)</td>
<td>8.1 (2.1)</td>
<td>8.1 (1.0)</td>
</tr>
<tr>
<td>Shoe Age (&gt;12 months)</td>
<td>11 (40%)</td>
<td>4 (27%)</td>
<td>6 (50%)</td>
</tr>
<tr>
<td>Baseline Shoe Asymmetry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rearfoot (mean)</td>
<td>Lateral (1 ± 3 mm)</td>
<td>Lateral (1 ± 2 mm)</td>
<td>Lateral (2 ± 4 mm)</td>
</tr>
<tr>
<td>Forefoot (mean)</td>
<td>Neutral (0 ± 2 mm)</td>
<td>Neutral (0 ± 2 mm)</td>
<td>Lateral (1 ± 2 mm)</td>
</tr>
</tbody>
</table>

8.4.2 Primary analysis: Feasibility

Findings for the primary outcomes used to assess the feasibility of the full study are reported on Table 8.2. The inclusion of 27 participants did not meet the targeted goal of 38 participants. Participant retention was considered low with a rate of only 56% (15/27) participants finishing the study. However, the participants who finished the half-marathon (n=15) had high adherence by completing 666 of 705 (94%) training sessions and 99 of 100 (99%) footwear assessments. Participants reported high satisfaction for study procedures (92%), time taken for footwear assessments (92%), and the training program (91%). Participants reported moderate satisfaction for the online training log and pain reporting tool (89%) and overall race results (80%) (Table 8.2). Barriers that made the training program difficult included work
(n=10, 71%), injury (new or pre-existing) (n=9, 64%), family (n=5, 36%) and weather (n=4, 29%). However, these barriers were overcome by: having a pre-planned program (n=11, 79%), improvements to their fitness (n=10, 71%), commitment to the study (n=10, 71%) and paying for the half-marathon race (n=7, 50%). Reasons for participant drop-out included over-commitment on time (n=5), injury (n=4), lost contact (n=2) and family emergency (n=1).

Table 8.2: Study Feasibility

<table>
<thead>
<tr>
<th>Factor</th>
<th>Result</th>
<th>Feasibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment</td>
<td>27/38 (71%)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Retention</td>
<td>15/27 (56%)</td>
<td>Low</td>
</tr>
<tr>
<td>Adherence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training</td>
<td>666/705 (94%)</td>
<td>High</td>
</tr>
<tr>
<td>Footwear Assessments</td>
<td>99/100 (99%)</td>
<td>High</td>
</tr>
<tr>
<td>Satisfaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Procedures</td>
<td>92% (range: 25-100)</td>
<td>High</td>
</tr>
<tr>
<td>Footwear assessment (time)</td>
<td>92% (range: 19-100)</td>
<td>High</td>
</tr>
<tr>
<td>Training program</td>
<td>91% (range: 13-100)</td>
<td>High</td>
</tr>
<tr>
<td>Online OSTRC tool</td>
<td>89% (range: 24-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Race results</td>
<td>80% (range: 34-100)</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

8.4.3 Secondary analysis: association between footwear and pain

8.4.3.1 Pain

A total of 171 lower limb problems were reported by the participants. Of these problems, 134 (78%) were reported with mild pain, 29 (17%) with moderate pain and eight (4%) with severe pain. The average pain severity across all participants was 6.0, SD ± 7.7 (scored 0-100). The knee was the most affected location of pain (36%) followed by the foot (26%), lower leg (11%), upper leg (10%), hip (8%), ankle (6%) and lower back (2%). Four participants withdrew from
the study due to problems related to the lower limbs during running – foot blister (n=1), lower back (n=1) considered severe pain, and ankle (n=1), knee (n=1) reported as moderate pain.

Table 8.3: Counts of lower limb problems by pain severity

<table>
<thead>
<tr>
<th></th>
<th>No pain (n=37)</th>
<th>Mild pain (n=41)</th>
<th>Moderate pain (n=17)</th>
<th>Severe pain (n=3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>18</td>
<td>7</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Week 3</td>
<td>6</td>
<td>9</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Week 6</td>
<td>6</td>
<td>12</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Week 9</td>
<td>3</td>
<td>6</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>Week 12</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

As part of the data collection instrument, participants reported problems to as many areas of concern during the prior week of training. However, participants were asked to indicate the area with the most concern. This area was used for the analysis of footwear asymmetry and is referred to as ‘pain side’. Similarly, the opposite side that was not indicated with an area of most concern was considered the ‘non-pain side’. Figure 10 presents the mean pain severity reported by participants for the area of most concern (pain side) at each of the main time points. Significant differences in mean pain severity were observed between baseline and week 3 (p = 0.01), baseline and week 9 (p = 0.00), baseline and week 12 (p = 0.01) and week 6 and week 9 (p = 0.01).

To gain a better understanding of the differences in TAS scores of the injured and non-injured sides over-time, a one-way ANOVA was conducted using the TAS (absolute, rearfoot and forefoot) as the independent variable and time as the dependent variable. Results from this analysis are presented in Appendix 21.
Figure 10: Mean pain severity over time. Error bars: 95% CI. * Significant difference from baseline. ** Significant difference from week 6

A simple scatter plot was developed to illustrate the distribution of Total TAS scores of the shoes with corresponding pain severity scores at each time point (i.e. if participant reported pain in the left knee, then the left shoe Total TAS was entered into the graph) (Figure 11). No apparent trends appear to be supported in the visual analysis of these data.
When looking at the effects of the independent variables (i.e. footwear measurements: TAS absolute, rearfoot, forefoot, and comfort) on pain reported over the 12-week assessment period, only the total TAS for the pain side $F(1, =18.01; p = 0.001)$ and non-pain side $F(1=39.78; p = 0.000)$ were significant. However, the effects of rearfoot TAS $F(1 = 0.40; p = 0.56)$, forefoot TAS $F(1, = 0.51; p = 0.82)$ comfort $F(1, = 1.94; p = 0.17)$ were not significant (Table 8.4).

### Table 8.4: Effect of independent variables and confounders on self-reported pain

<table>
<thead>
<tr>
<th>Variables</th>
<th>(df) F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Independent Variables</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injured side Total TAS</td>
<td>(1, 13.70) 18.01</td>
<td>0.001*</td>
</tr>
<tr>
<td>Injured side Rearfoot TAS</td>
<td>(1, 4.80) 0.40</td>
<td>0.559</td>
</tr>
<tr>
<td>Injured side Forefoot TAS</td>
<td>(1, 52.00) 0.78</td>
<td>0.38</td>
</tr>
<tr>
<td>Non-injured side Total TAS</td>
<td>(1, 33.14) 39.78</td>
<td>0.000*</td>
</tr>
<tr>
<td>Non-injured side Rearfoot TAS</td>
<td>(1, 9.29) 0.46</td>
<td>0.52</td>
</tr>
<tr>
<td>Non-injured side Forefoot TAS</td>
<td>(1, 52.00) 0.51</td>
<td>0.82</td>
</tr>
<tr>
<td>Comfort</td>
<td>(1, 95.00) 1.94</td>
<td>0.17</td>
</tr>
</tbody>
</table>
Confounding Variables
Participant age (1, 98.00) 0.10 0.75
BMI (1, 98.00) 2.78 0.10
FPI (mean) (1, 98.00) 0.64 0.80
Gait pattern (1, 98.00) 0.40 0.53
Running experience (1, 98.00) 1.54 0.22
Previous injury (1, 98.00) 0.72 0.79
Shoe age (1, 30.70) 0.40 0.84

df degrees of freedom (numerator, denominator)
* indicates significant values (p < 0.05)

8.4.3.2 Absolute TAS scores

Figures 12-15 indicate the changes in mean scores for each of the footwear variables over the 5 timepoints in this study. Key findings indicate there were no large differences between means at any time point. Absolute TAS scores at baseline ranged from 1 mm to 11 (mean 4 mm, ± 2 mm) of asymmetry. Changes to absolute TAS scores for both the pain side and non-pain side overtime are presented in Figure 12.

![Total TAS Scores Over Time](image)

Figure 12: Change in Total TAS over time. Negative values indicate medial asymmetry (skew). Positive values indicate lateral asymmetry (skew).
8.4.3.3 Rearfoot TAS scores

At baseline, 16 individual shoes had rearfoot medial asymmetries (medial skew) ranging from 1 mm to 4 mm, 33 had rearfoot lateral asymmetries (lateral skew) ranging from 1 mm to 9 mm and five shoes had neutral rearfoot TAS scores (had neither medial nor lateral asymmetries) (Appendix 22). The change in mean rearfoot TAS scores over time are presented in Figure 13.

Figure 13: Change in rearfoot TAS scores over time. Negative values indicate medial asymmetry (skew). Positive values indicate lateral asymmetry (skew). Error bars 95% CI

8.4.3.4 Forefoot TAS scores

Nineteen shoes had forefoot medial asymmetries ranging from 1 mm to 4 mm, 25 shoes had forefoot lateral asymmetries ranging from 1 mm to 8 mm and nine shoes had neutral forefoot
TAS scores (Appendix 22). The change in mean forefoot TAS scores over time are presented in Figure 14.

![Figure 14: Change in forefoot TAS scores over time. Negative values indicate medial asymmetry (skew). Positive values indicate lateral asymmetry (skew).](image)

### 8.4.3.5 Footwear comfort

The average of all comfort variables (n= 9) for each participant was used for the analysis. The lowest comfort scores at each time point were: 51, 45, 42, 39 and, 40 (out of 100 arbitrary units) at baseline, week 3, week 6, week 9 and week 12, respectively. Comfort slightly decreased over the 12-week period. The changes in mean comfort scores over time are presented in Figure 15.
8.5 Discussion

8.5.1 Feasibility

This feasibility study resulted in the recruitment of 27 eligible participants, a retention rate of 56%, and participant satisfaction rates ranging from 80-92%. Based on these findings, the current study is not feasible and requires modification to the recruitment and retention of participants.

The recruitment goal for this study was 38 participants which accounted for a 20% drop-out rate (based on previous data [47, 50]. A sample size of 38 would allow for conducting a mixed-effect model with three to four covariates (10 participants per factor rule) to be explored in the statistical model. However, the recruitment methods over a 10-week period only resulted in 27 total participants, 15 of which completed the study.
The low recruitment rate could have been due to the demographics of Dunedin. According to 2013 census data there are 56,460 people living in Dunedin between the ages of 18 and 55 that would have been eligible for this study. Additionally, based on data from New Zealand sport participation survey, 19% of New Zealanders participate in recreational running but only 12% participate in fun-runs or other running events [15]. Given these figures 6,775 people in Dunedin were likely to participate in this study, if they became aware of it through the adverts placed in local running and fitness clubs and displayed on social media websites.

The language used in the advertisements could have been a factor in the recruitment of participants. The advertisements requested novice runners to participate in a half marathon. It is possible that novice runners would be more committed and motivated to participate in shorter races (i.e. 5k or 10k events), and that recreational runners would be a more suitable population for half-marathon distances [27, 29].

The high drop-out rate (44%) may be due to the experience level (novice) of the participants, although drop-out rates of recreational runners have been observed as low as 13% [48]. One study that indicated similar drop-out rates (47%) [254] of novice runners, but they were involved in additional strength training interventions during a 6-month follow-up period. For the cohort in this study, the primary reason for drop-out was related to the time required for the training program. Interestingly, the adherence to the training program was high (94%) among the participants. It is likely that novice runners were unaware of the time commitment involved in training for a half-marathon and dropped out of the study upon realising they could not sustain the training load. Studies involving similar methods had drop-out rates of 23.1% [47] for a 16-week graduated half-marathon training program and 23% [50] for a 13-week half-marathon training program including a women-only cohort.
8.5.2 Data collection methods

The cohort in this study indicated high satisfaction of study procedures (92%) and moderate satisfaction for the use of the online pain reporting (OSTRC) tool (89%). Indeed, the OSTRC tool was used in this study for several reasons. The purpose of the OSTRC tool is to allow researchers and clinicians to monitor and determine the degree of pain from non-specific overuse injuries at regular intervals [38]. Further, the OSTRC tool collects more than 10 times the pain data of overuse injuries than traditional methods [38]. It also collects data on regional anatomical locations rather than specific injury types, allowing the cohort to report any problems they have experienced and reducing the limitations of defining injury.

8.5.3 Data Analysis

The missing-data from participant drop-out creates unbalanced data sets. If dropout processes are not handled correctly, the data can show a false increase of the mean response (i.e. association of TAS to pain) over time [255]. The linear mixed model used in this study allowed participants with missing data to be included [253]. It was also able to handle the within-participant and between-time variability observed by multiple repeated measures [253]. Other methods of handling missing data include: multiple imputation, last observation carried forward and complete case analyses [255].

It was not possible to complete a linear mixed-model analysis due to the small sample size in this study. Advantages of using a linear mixed model that may benefit a fully-powered study include the ability to cluster participants into sub-groups, account for continuous time variables and incorporate unbalanced repeated measures [256].
8.5.3.1 Alternative data analysis

In the alternative analysis which explored the association between each factor (independent variables, participants’ age, BMI, FPI, gait pattern, running experience, previous injury and shoe age), only the cumulative TAS scores for both the injured and non-injured sides reached statistical significance. The cumulative TAS scores were composite scores from the rearfoot and forefoot measurements. Given this, it is likely that the rearfoot and forefoot scores would yield statistically significant results in a fully-powered study.

8.6 Strengths and limitations

The current study aimed to determine the feasibility of assessing asymmetric footwear among novice runners. Strengths of the study design include high adherence and participant satisfaction with the standardised training program and footwear assessments. The training program included gradual (10%) weekly increases and incorporated a variety of training techniques (interval, tempo, and long runs).

Participants adhered to and enjoyed the training program however, their satisfaction with the race-results was moderate (80% satisfaction). This could be due to the weather during the half-marathon, as cold temperatures (8° C) and rain were present during the majority of the race. Weather was also indicated as a barrier to the training program. The half-marathon took place in September 2017, which required the bulk of the training program to be conducted during the winter months (in the Southern Hemisphere). Therefore, several participants chose to run indoors on treadmills or indoor tracks. Others completed training during darkness before or after work or spent time mid-day to utilise daylight hours for training.
Concerning the high adherence and satisfaction to footwear assessments, only one participant did not attend a footwear assessment session. The high adherence to these sessions could be due to the instructions given during baseline testing, emphasising the importance of the footwear assessments to the study. Participants also expressed an interest in the TAS scores and the changes from previous assessments. Non-significant changes in TAS scores were observed among the cohort. However, during the footwear assessments, the primary researcher explained the individual footwear measurements and changes to the participants, thus further encouraging attendance to the assessment sessions.

The primary limitation of this study is the low sample size. Advertisements for the study were displayed at local gyms and fitness facilities as well as running-club rooms and social media pages. We did not assess how the participants came to know about the study however, the all-female cohort is unexpected, given that in New Zealand, men are more likely than women to be a member of a gym or sports club [15]. It is possible that the 10-week recruitment period was not long enough or the medium for displaying advertisements did not reach enough people to capture an adequate sample of participants. Similar studies had recruitment periods of 8 weeks [47, 148], but used newspaper advertisements or word of mouth to recruit participants, they were also located in population dense areas (Amsterdam and Vancouver) [50, 148, 254]. Other recruitment strategies in the literature include contacting participants that are already registered for an event [27, 29] or are part of an established database of runners [257]. Additionally, while the current study posted the recruitment advert to running club social media pages, we did not pay for any advertising on Facebook. The use of Facebook advertising with specific sociodemographic targeting can accelerate recruitment and access potential participants [258].
8.7 Conclusions

Based on the results of this feasibility study, conducting a full-sized prospective cohort study assessing the association of footwear TAS to RRI is not feasible in Dunedin, New Zealand. Participants who completed the current study found the training study procedures, including the time required for footwear assessments to be satisfactory. Furthermore, adherence to the training programme and attendance at footwear assessments was high (>90%). However, for the current study to be feasible, modifications to the recruitment methods are needed to capture a greater number of participants and handle a drop-out rate of 44%.

8.8 In the next Chapter

Chapter 9 is the last chapter of this thesis and will review the findings of the studies in Chapters 3-8. It will also provide a robust discussion on the role of the TAS in the footwear micro-system and future research directions.
9 CHAPTER 9: DISCUSSION

9.1 Chapter Overview

The final Chapter of this thesis reviews the findings of the work completed in the previous Chapters. It also provides a discussion of how this research contributes to the footwear micro-system and how it can inform future research projects in this area. The strengths and limitations of this PhD project are presented prior to the final conclusions.

9.2 Reviewing the Chapters

Chapters 3-8 of this thesis highlighted the need for and use of objective footwear assessments in research and clinical settings. The Chapters aimed to explore the role of footwear on RRI in the context of the footwear micro-system, by addressing five specific research questions:

1. What are the methods and tools currently used for assessing footwear on running-related injuries? Are they effective tools?
2. What factors influence runners’ footwear choices?
3. How do clinicians perceive footwear when assessing and treating patients with running-related injuries?
4. Is the footwear total asymmetry score tool a reliable assessment of mediolateral asymmetry?
5. Is it feasible to conduct an observational study for determining the association between footwear asymmetry and RRI among runners?
Chapter 2 described three selected footwear assessment tools [22, 23, 140] currently available in the literature. This Chapter presented a background and introduction to the systematic reviews in Chapters 3 and 4.

Chapter 3 was the first of two systematic reviews evaluating footwear in RRI research. It focused on the tools used in current literature to assess footwear characteristics. The review included 26 studies with various designs to capture a wide scope of the methods used in clinical and controlled research. The methodological quality was poor in more than half of the studies and only limited conclusions could be drawn. Out of nearly 30 different footwear characteristics reported, only one valid tool was used to determine three different footwear characteristics [22]. Findings from this study highlighted a gap in the scientific literature in need of strengthening. Footwear characteristics are not objectively evaluated among studies examining the relationships of footwear on RRI.

Chapter 4 assessed the level of evidence between footwear characteristics and RRI. Due to high heterogeneity between studies, traditional meta-analyses were not possible. Based on a pragmatic approach, there is only low- to no-evidence supporting the relationships between footwear characteristics and RRI. This Chapter further contributes to identifying a gap in the literature. It highlights that the assessment of footwear is not standardised and there is high heterogeneity between studies. Thus, a proper assessment of the effects of footwear on RRI cannot be assessed.

Chapter 5 explored an area that has received little attention in the RRI discipline. A qualitative analysis was undertaken, to evaluate the factors influencing runners’ footwear choices. Using a general inductive approach, three themes emerged from the data indicating that runners are influenced by: economics, other people and the runner’s own needs. Most runners spend time gathering information from media, fellow runners, and trial-and-error to inform their footwear choices. Runners with less than five years’ experience, generally choose
their footwear based on instinct or brand loyalty and are less sceptical of marketing gimmicks than runners with more than five years of experience. Veteran runners typically have more than one pair of shoes in circulation at a time. They also base their purchasing decisions on design specifications rather than brand/model loyalty and are willing to try other brands as long as the shoe meets their needs. This is likely because a veteran runner has had greater experience with various footwear and injuries. Gender differences were also present. Women runners were generally more concerned with the performance and comfort of footwear while men tended to focus on fit.

Chapter 6 also used a qualitative approach to understand clinician’s perspectives of footwear in their assessment and management of runners with RRI. Again, three main themes emerged from the data indicating clinicians: have inconsistent footwear assessment techniques, rely on patient’s barefoot performance, and use footwear for treatment. This study highlighted that most clinicians lack clear strategies on how to assess and prescribe footwear to manage RRI. Clinicians understand that footwear can influence injury, and that replacing footwear can be a simple and inexpensive treatment. However, with the exception of one clinician, the participants in this study assess the patient and their footwear separately and can only make inferences to how the footwear are affecting the patient. The outlier clinician in this study describes using objective assessments of the patient’s footwear to determine the mediolateral asymmetry caused be either design or degradation. The clinician then compares the patient’s performance of dynamic tasks when barefoot to their performance of the same tasks while shod. Any discrepancies from the barefoot performance are correlated to the asymmetry scores of the patient’s shoes and can be used to inform treatment. Treatment may include modifying or replacing footwear so that the patient’s performance of dynamic tasks while shod are parallel to their performance while barefoot.
In summary, access to and knowledge of objective footwear measurements could improve the decision-making process for clinicians when assessing and managing patients with RRI. Combining these findings with the literature reviews, provides a solid background and support for the subsequent Chapters: the reliability of the footwear total asymmetry score tool (TAS), and the feasibility of an observational study assessing the role of asymmetric footwear on the onset of RRI.

**Chapter 7** evaluated the reliability of the TAS tool as described by the outlier clinician in Chapter 4. The expert clinician trained the research team on how to assess footwear asymmetries. The assessment included quantifying the thickness and hardness of footwear inner-, mid- and outer-soles using a digital calliper and durometer, respectively. Results revealed excellent within-rater, between-rater and between-day reliability of the TAS. It also indicated a wide generalisability of findings, as novice raters can obtain similar results as expert raters. This study was accepted for publication in *Footwear Science* [130].

**Chapter 8** assessed the feasibility of an observational study evaluating the role of asymmetric footwear on RRI. The recruitment of an all-women cohort (n=27) fell short of the target goal of 38 participants. Additionally, the study experienced a higher drop-out rate (44%) than projected. However, among the participants who completed the half-marathon standardised training program (n=15), the adherence rate was 94% and only one participant missed a footwear assessment. In summary, conducting a full-sized observational cohort study that examines the effects of footwear asymmetry on RRI, is not feasible in Dunedin, New Zealand. However, this study describes a novel approach to assessing footwear and may be useful among other research groups in the footwear micro-system.
9.3 Contribution to the footwear micro-system

This PhD project contributes to three main objectives of the footwear micro-system by: identifying the assessment and reporting of footwear characteristics are in need of strengthening, examining indirect effects of the footwear micro-system on RRI and presenting a novel strategy to assess footwear in the presence of RRI.

9.3.1 Identify areas of the footwear micro-system in need of strengthening

This thesis identified that methods of assessing and reporting footwear characteristics is not standardised among studies of RRI (Chapters 3 and 4). This can be attributed to a lack tools to assess the characteristics of footwear designed for running. It is also plausible that footwear characteristics are not adequately assessed in other sub-systems (e.g. biomechanics or performance) because attention is focused on identifying inherent faults of the runner (Chapter 6).

Strengthening the footwear assessment component of the running-injury system may advance the understanding of the effects of footwear on runners. For example, consider a recent narrative review which argues that running with a forefoot strike pattern in minimalist shoes can change the course of RRI [79]. The authors highlight selected studies that show positive interactions between footwear and strike patterns. However, the external validity of the studies in the review by Davis et al [79] may be compromised due to inconsistent use of footwear nomenclature and therefore, results are affected by differences in footwear that were not adequately measured. Inconsistent footwear reporting is also present in biomechanical studies that have assessed the effects of footwear on discrete movement variables among runners [42, 53, 111, 117, 121, 123, 186, 233, 259-261]. It is contended that using the TAS to assess footwear may advance the RRI discipline by: (1) improving the
functionality within the footwear microsystem (2) providing a control and feedback mechanism to inform relevant actors within and between hierarchies, and (3) becoming tool to catalyst a shift of focus on injury aetiology from a person-centred to a system-centred approach.

9.3.2 Examine indirect effects of the footwear micro-system on RRI

Understanding the motivations and goals that prompt certain behaviours is an important objective of systems-based research [36, 80, 83, 91, 193]. It allows indirect relationships to emerge that may not have been recognised when identifying causal risk-factors [81].

As described in Chapters 5 and 6, multiple factors influence runners choices of footwear and clinicians have varying perceptions regarding footwear in the assessment and management of RRI. Chapter 5 highlighted that factors such as cost and availability influence runners’ footwear choices, while Chapter 6 indicated that most clinicians are unclear about their assessments of footwear when managing RRI. Taking these factors a step further with systems-based thinking provides an alternative perspective of how the footwear microsystem, in New Zealand, may be indirectly affecting RRI. In New Zealand, there are no national footwear manufacturers for any of the major running shoe brands, therefore, footwear is imported from various suppliers around the world. Additionally, the government inflicts high Goods and Services Tax (GST) on imported items, causing an increase in retail prices and a limited number of models available [173, 262, 263]. Due to the high cost of footwear, runners are likely to choose cheaper shoes or wear shoes longer than runners in countries where the cost of footwear is lower or where a wider range of styles and models are available. Indeed, a potential relationship exists between worn footwear and RRI [111], but requires further assessment. Currently, clinicians lack assessment tools that would enable them to assist
runners in recognising when to replace footwear and which shoes they should actually be buying. Although this ‘top-down’ perspective cannot be generalised to other geographic regions, it might offer valuable information within the context of the running-injury system in New Zealand.

9.3.3 Proposing novel injury interventions

This thesis demonstrated the use of the reliable TAS tool (Chapter 7) to assess footwear asymmetry among runners in a prospective observational study (Chapter 8). Using the TAS to monitor footwear over-time may help inform interventions where modifying or replacing footwear can prevent injury. A viewpoint acquired from complex industrial systems suggests that a ‘maintenance domain’ is a key contributor to ensuring the safety and continued operation or performance of a system [264]. Adopting this view into the footwear micro-system could allow clinicians and researchers to use the TAS to guide footwear maintenance procedures.

Indeed, effective tools (e.g. TAS) are needed to identify, remove, control and/or prevent hazards (e.g. footwear asymmetries) for ensuring the safety and performance of the runner. Currently, there are no available studies to suggest how footwear asymmetries can be adjusted, or thresholds for when to replace footwear. However, it is crucial for users (e.g. clinicians) to have sufficient knowledge and skills when measuring footwear so that proper maintenance (e.g. adjusting/replacing footwear) can be conducted [264]. Chapter 7 revealed that novice and expert raters can reliably determine footwear TAS scores.

Unlike the well-established industrial systems, with clearly defined maintenance personnel and safety and resource management teams, the relevant actors in the footwear micro-system are currently unclear. Establishing this requires identifying the relationships
within and between hierarchies by further developing the footwear micro-system [81, 83]. The idea of using the TAS to inform footwear maintenance may be carried forward in future systems-based research.

### 9.4 Future Research

This PhD project identified several knowledge gaps and areas for future research. Many of these are described within the respective chapters. However, when thinking about the overall footwear micro-system, a few additional recommendations for future research are presented.

#### 9.4.1 Evaluate effect of asymmetric footwear on RRI

Identifying significant aetiological factors of RRI is a critical component of systems-based research. Without knowledge of the risks associated to runner, effective treatment and prevention strategies cannot be developed [83]. Conducting large prospective cohort studies is challenging but yields high results when identifying risk factors. Although improvements are needed to increase participant recruitment, some components (i.e. TAS assessments, training program, OSTRC reporting tool) from Chapter 8 could be useful when developing a protocol to assess the effects of asymmetric footwear on RRI.

#### 9.4.2 Determine thresholds for TAS scores

Currently, data suggests that asymmetries as little as 1mm can affect balance and neuromuscular feedback [128] as well as plantar pressure profiles [170]. Additionally, asymmetries of up to 8 mm have been observed [165, 170]. However, there is limited data regarding how much asymmetry is clinically or statistically significant in regards to injury or
other related outcomes (i.e. performance, biomechanics). If widespread use of the TAS tool is adopted data can be collated to determine thresholds in clinical and research observations of footwear and RRI. This is a project that would require large amounts of data to capture several types of footwear and runners, ideally a systematic review and meta-analysis. Indeed, this would require further original studies evaluating the effects of asymmetric footwear on RRI.

9.4.3 Develop the footwear micro-system model

As highlighted in Chapter 1, the structure of the footwear micro-system was speculated based on previous work describing similar systems. Further work is needed to develop a validated model that describes the relationships and influences of the many actors within the footwear micro-system. This would best be done with a cohesive multidisciplinary group of RRI epidemiologists, footwear specialists, clinicians, and systems ergonomists [83]. Advanced analysis would identify the level of influence from the footwear micro-system within the running-injury system.

9.4.4 Apply the TAS to injury frameworks

A major limitation to systems-based research is implementing effective policies and procedures [88, 93]. Again this is an area requiring multidisciplinary approaches. However, current sports injury frameworks (e.g. TRIPP) could adopt the TAS into the reporting and surveillance of footwear among sports injuries. This would generate a greater use of the TAS in clinical and research settings of multiple sports.
9.5 **Strengths of this thesis**

Although systems-based research has been applied to health [265-269], public safety [101, 270-272] and some sport domains [105, 125, 273], it is new to the context of running-related injuries [81]. This thesis embraced emerging theories of the running-injury system and used a pragmatic approach to combine traditional epidemiological research with a systems-based perspective to better understand the role of footwear in RRI. While this thesis demonstrated the practical use of the TAS tool, it also suggests that the TAS tool has a role in improving the overall function of the footwear micro-system and ultimately the running-injury system.

A strength of this thesis is the use of multiple study designs to gain understanding of various components of the footwear micro-system, how they interact and bridge the gap between theory and practice. The systematic exploration of the literature in Chapters 3 and 4 helped identify that footwear assessments are inconsistent and ineffective in current research methods of footwear and RRI. The qualitative analyses in Chapters 5 and 6 described that runners’ behaviours towards footwear as an injury prevention strategy are different than clinician’s perceptions of footwear in the treatment and management of RRI. Assessing the reliability of the TAS tool, in Chapter 7 and applying it to an observational cohort feasibility study, in Chapter 8, presented a novel method of assessing footwear in a field-based setting.

If footwear characteristics and RRI are related, this thesis proposes that RRI rates (incidence/prevalence) can be decreased if key components can be manipulated. To determine the relationships between footwear characteristics and RRI, a fully powered observational study needs to be conducted.

**Clinicians should adopt the use of the TAS tool:** Clinicians’ perceptions of footwear influence runners’ opinions on footwear and may help guide runners to make informed decisions about their running footwear. Monitoring asymmetry may help runners buy new footwear at the
right time. If appropriate (i.e. if footwear asymmetry increases the risk of RRI), clinicians could then educate runners about footwear asymmetry and enable runners to making better-informed choices in initial footwear purchases, recognise whether and when to switch to a different model or design, and/or when to replace footwear.

**Runners should think differently about footwear asymmetry:** From the literature, asymmetric design does not influence RRI [137]. The role of asymmetry due to wear is not understood, runners should be aware of their wear patterns and possibly with the assistance of a clinician how the density of the sole changes over time. Being conscious of this may be the first step in recognising footwear is inappropriate or needs replacing.

**Running shoe manufacturers should invest in understanding footwear asymmetry:** Again, if footwear asymmetry increases the risk of RRI, footwear manufacturers could have a powerful influence on reducing RRI risk. In a competitive marketplace, the brand that follows the evidence has the best chance of influencing RRI. Companies could benefit from conducting internal research with the aim of understanding the role of their footwear in RRI, rather than marketing gimmicks. However, for this to work runners need to value companies that operate in a way that addresses systems-based objectives.

The Chapters contained in this thesis are written as manuscripts so that they can be submitted for publication and contribute to the body of knowledge on the role of footwear in the footwear micro-system. Chapter 7 has already been published in a well-known journal among footwear researchers, *Footwear Science*. Additionally, Chapter 3 is currently under review in the *Journal of Sport Sciences*. Manuscripts for Chapters 4-6 and 8 have been prepared and will be submitted to suitable journals during the bursary period following the submission of this thesis. Each manuscript emphasises the practical or theoretical need for objective footwear measurements and encourages additional use of the TAS tool.
Appropriate reporting guidelines were used for Chapters 3, 4, 5, 6 and 8. The PRISMA statement ensured the robust reporting of the systematic review search methods, data analysis, and results. The Downs and Black quality checklist was also used in Chapter 3 to determine the methodological quality of the included studies. The CORE-Q checklist was used to report the methods and findings of Chapters 5 and 6. The comprehensive 32-item checklist is one of only a few publisher-supported guidelines. Chapter 8 utilised the STROBE statement for cross-sectional studies. Although Chapter 8 was a feasibility study, using the STROBE statement ensured that adequate information was presented to inform a full-sized trial.

9.6 Limitations to this thesis

Given that the running-injury system is in its infancy [81, 83] and the footwear micro-system was conceptualised in Chapter 1, the theoretical framework guiding this thesis is not yet developed. Therefore, it cannot inform which areas of the running-injury system need to be addressed. However, the studies chosen for this PhD project used traditional epidemiological methods to contribute to objectives, highlighted by systems-based research [81, 83], to improve the understanding of RRI.

This thesis contains both qualitative and quantitative methods, however, it is not a true mixed-methods thesis. The participants in the qualitative studies, specifically the runners, were a separate group of individuals not involved in any other aspect of this project. Chapter 8 briefly speculated that the TAS may not be useful to novice women runners. This was based on the interviews results of Chapter 5, in which experienced men runners described utilising specific measurements to inform their footwear choices, whereas women did not. A more detailed understanding of the usefulness of the TAS tool among novice women runners could have been gained from a qualitative analysis following the feasibility study.
Validity of the TAS was not measured in this thesis. Criterion based validity could not be assessed as there are currently no gold-standards for measuring footwear asymmetry. The TAS is intended to measure the asymmetry of the inner-, mid- and outer-soles caused through either design or degradation [124, 165]. The tools used to measure thickness (digital calliper) and hardness (durometer) have previously been established for the purposes used in this thesis. Further clinical and research uses of the TAS are needed to determine outcomes that would allow predictive validity of the TAS to be established.

9.7 Conclusion

This PhD thesis explored the use of footwear measurements in research and clinical settings and contextualised the findings using a systems-based perspective to treat and prevent RRI. Despite the availability of multiple footwear assessment tools in the literature, the use of valid and reliable methods to measure footwear characteristics is minimal from academic and clinical literature. Furthermore, clinicians lack evidence-based methods to assess the footwear of injured runners. Runners seek information from multiple sources to guide their footwear choices but are often limited by factors specific to the geographic region of New Zealand. The TAS tool can reliably measure the mediolateral asymmetry of footwear caused by design and/or degradation. Based on findings from this thesis, it is not feasible to conduct a full-sized trial to assess the effects of asymmetric footwear on RRI, unless modifications are made to address limitations observed with recruitment and retention of participants.

These findings highlight that runners in New Zealand are part of a complex sociotechnical system with many actors influencing the development of RRI. Using the TAS tool may allow clinicians and researchers to effectively evaluate runners’ footwear to inform
possible treatment and prevention strategies. Future multidisciplinary work is needed to understand the structure and impact of footwear within the running-injury system.
10 REFERENCES


101. Scott-Parker, B., N. Goode, and P. Salmon, *The driver, the road, the rules ... and the rest? A systems-based approach to young driver road safety*. Accident Analysis & Prevention, 2015. 74: p. 297-305.
103. Hulme, A., *Theoretical perspectives on using epidemiology and systems thinking to better understand the aetiology and prevention of distance running-related injury*, in *School of Health Sciences and Psychology*. 2017, Federation University Australia.


258. King, D.B., N. O'Rourke, and A. DeLongis, *Social media recruitment and online data collection: A beginner’s guide and best practices for accessing low-prevalence and


## 11 APPENDICES

Appendix 1 PRISMA reporting checklist

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist Item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
</tr>
<tr>
<td><strong>Abstract</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS)</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., web address), and, if available, provide registration information including registration number.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening eligibility, included in systematic review, and, if applicable included in the meta-analysis.</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
</tr>
<tr>
<td>Data items</td>
<td>11</td>
<td>List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>12</td>
<td>Describe methods used for assessing risk of bias of individuals studies (including specification of whether this was done at the study or</td>
</tr>
<tr>
<td>Section</td>
<td>Item</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Study selection</strong></td>
<td>17</td>
<td>Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</td>
</tr>
<tr>
<td><strong>Study characteristics</strong></td>
<td>18</td>
<td>For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.</td>
</tr>
<tr>
<td><strong>Risk of bias within studies</strong></td>
<td>19</td>
<td>Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).</td>
</tr>
<tr>
<td><strong>Results of individual studies</strong></td>
<td>20</td>
<td>For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
</tr>
<tr>
<td><strong>Synthesis of results</strong></td>
<td>21</td>
<td>Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
</tr>
<tr>
<td><strong>Risk of bias across studies</strong></td>
<td>22</td>
<td>Present results of any assessment of risk of bias across studies (see item 15).</td>
</tr>
<tr>
<td><strong>Additional analysis</strong></td>
<td>23</td>
<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16])</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td>24</td>
<td>Summarize the main findings including the strength of evidence for each main outcomes; consider their relevance to the key groups (e.g., healthcare providers, users, and policy makers).</td>
</tr>
<tr>
<td><strong>Limitations</strong></td>
<td>25</td>
<td>Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).</td>
</tr>
<tr>
<td><strong>Conclusions</strong></td>
<td>26</td>
<td>Provide a general interpretation of the results in the context of other evidence, and implications for future research.</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>27</td>
<td>Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.</td>
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## Appendix 2: Systematic review search strategy

<table>
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<th>SCOPUS</th>
<th>Science Direct 2007 to present</th>
<th>EMBASE 1947 to present with daily update</th>
<th>Web of Science Core collection All years</th>
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<td>Population</td>
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<td>1. Run*</td>
<td>1. Run*</td>
<td>1. Running/</td>
<td>1. run*</td>
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<tr>
<td></td>
<td>2. Shoe/</td>
<td>2. Shoe OR footwear</td>
<td>2. Shoe OR footwear</td>
<td>2. shoe/</td>
<td>2. Shoe OR footwear</td>
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<td>1 AND 2 AND 3 (Title-Abs-Key)</td>
<td>1 AND 2 AND 3 [All sources (sports and recreation)]</td>
<td>1 AND 2 AND 3</td>
<td>1 AND 2 AND 3</td>
</tr>
</tbody>
</table>

| Initial search results: 15 September 2016 | 494 | 2246 | 1178 | 679 | 1217 |
| Updated search results: 4 September 2017 | 15  | 69  | 121 | 14  | 230 |
## Appendix 3: Brand/model and nomenclature of reported footwear

<table>
<thead>
<tr>
<th>Brand/model</th>
<th>Nomenclature reported</th>
<th>Reference</th>
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<td>Adidas Supernova Glide 3</td>
<td>Neutral</td>
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<td>Traditional</td>
<td>Dubois, B. et al. 2015</td>
</tr>
<tr>
<td>ASICS Gel Cumulus</td>
<td>Conventional</td>
<td>Fuller, J.T. et al. 2017</td>
</tr>
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<td>ASICS Gel Cumulus</td>
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<td>Knapik, J.J. et al. 2009</td>
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<td>Motion Control</td>
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<td>ASICS Nimbus</td>
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<td>Motion Control</td>
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</tr>
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<td>Standard Cushioned</td>
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<tr>
<td>Mizuno Wave Rider</td>
<td>Traditional</td>
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<td>Mizuno Wave Universe</td>
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<tr>
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<td>Motion Control</td>
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<td>Partial-minimalist</td>
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</tr>
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<td>Vibram 5-Finger Bikila</td>
<td>Full-minimalist</td>
<td>Ryan, M.B. et al. 2014</td>
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<td>Vibram FiveFingers</td>
<td>Barefoot-simulating</td>
<td>Giuliani, J. 2011</td>
</tr>
</tbody>
</table>
Appendix 4: School of Physiotherapy ethical approval for qualitative studies

Memorandum/Manatu

To/Ki a: Dr Gisela Sole
From/Nā: Professor Leigh Hale
C.C/He kape mā: 12 November 2015
Date/Te rā: "Management of overuse running injuries of the knee and the role of footwear: Physiotherapists', Podiatrists' and runner perspectives."
Re/Te Kaupapa: Ref: SoP/EC/2015/07

Dear Gisela,

I am pleased to advise you that your application to the School of Physiotherapy Ethics Committee has been recommended for endorsement by the University Ethics Committee.

Please note that full approval does not take effect until you have written confirmation from them that this project may proceed.

If the nature, consent, location, procedures or personnel of your approved application change, please advise the Acting Chair (Dr Hilda Mulligan) in writing.

Yours sincerely

[Signature]

Professor Leigh Hale
Dean
School of Physiotherapy
Appendix 5: University of Otago ethical approval for qualitative studies

Dear Dr Sole,

I am writing to confirm for you the status of your proposal entitled ‘Management of overuse running injuries of the knee and the role of footwear: Physiotherapists’, Podiatrists’ and runners’ perspectives’, which was originally received on November 17, 2015. The Human Ethics Committee’s reference number for this proposal is D15/375.

The above application was Category B and had therefore been considered within the Department or School. The outcome was subsequently reviewed by the University of Otago Human Ethics Committee. The outcome of that consideration was that the proposal was approved.

Approval is for up to three years from the date of HOD approval. If this project has not been completed within three years of this date, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8556
Email: gary.witte@otago.ac.nz
Appendix 6: Māori consultation for qualitative studies

Tuesday, 13 October 2015.

Dr Gisela Sole,
School of Physiotherapy,
DUNEDIN.

Tēnā Koe Dr Gisela Sole,

**Influence of footwear on overuse knee injuries in runners**

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 13 October 2015 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outlined in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

As this study involves human participants, the Committee strongly encourage that ethnicity data be collected as part of the research project. The questions on self-identified ethnicity and descent, these questions are contained in the latest census.

The Committee suggests dissemination of the research findings to relevant Māori health organisations regarding this study, including Taeora Tinana, Māori Physiotherapists within the New Zealand Society of Physiotherapists.

We wish you every success in your research and the committee also requests a copy of the research findings.
## Appendix 7: Consolidated criteria for reporting qualitative studies (COREQ)

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Guide questions/description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Domain 1: Research team and reflexivity</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Personal Characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Inter viewer/facilitator</td>
<td>Which author/s conducted the interview or focus group?</td>
</tr>
<tr>
<td>2.</td>
<td>Credentials</td>
<td>What were the researcher’s credentials? E.g. PhD, MD</td>
</tr>
<tr>
<td>3.</td>
<td>Occupation</td>
<td>What was their occupation at the time of the study?</td>
</tr>
<tr>
<td>4.</td>
<td>Gender</td>
<td>Was the researcher male or female?</td>
</tr>
<tr>
<td>5.</td>
<td>Experience and training</td>
<td>What experience or training did the researcher have?</td>
</tr>
<tr>
<td></td>
<td><strong>Relationship with participants</strong></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Relationship established</td>
<td>Was a relationship established prior to study commencement?</td>
</tr>
<tr>
<td>7.</td>
<td>Participant knowledge of the interviewer</td>
<td>What did the participants know about the researcher? E.g. personal goals, reasons for doing the research</td>
</tr>
<tr>
<td>8.</td>
<td>Interviewer characteristics</td>
<td>What characteristics were reported about the interviewer/facilitator? E.g. Bias, assumptions, reasons and interests in the research topic</td>
</tr>
<tr>
<td></td>
<td><strong>Domain 2: study design</strong></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Methodological orientation and Theory</td>
<td>What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</td>
</tr>
<tr>
<td></td>
<td><strong>Theoretical framework</strong></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Sampling</td>
<td>How were participants selected? E.g. purposive, convenience, consecutive, snowball</td>
</tr>
<tr>
<td>11.</td>
<td>Method of approach</td>
<td>How were participants approached? E.g. face-to-face, telephone, mail, email</td>
</tr>
<tr>
<td>12.</td>
<td>Sample size</td>
<td>How many participants were in the study?</td>
</tr>
<tr>
<td>13.</td>
<td>Non-participation</td>
<td>How many people refused to participate or dropped out? Reasons?</td>
</tr>
<tr>
<td></td>
<td><strong>Setting</strong></td>
<td></td>
</tr>
<tr>
<td>14.</td>
<td>Setting of data collection</td>
<td>Where was the data collected? E.g. home, clinic, workplace</td>
</tr>
<tr>
<td>15.</td>
<td>Presence of non-participants</td>
<td>Was anyone else present besides the participants and researchers?</td>
</tr>
<tr>
<td>16.</td>
<td>Description of sample</td>
<td>What are the important characteristics of the...</td>
</tr>
</tbody>
</table>
**Data collection**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17. Interview guide</td>
<td>Were questions, prompts, guides provided by the authors? Was it pilot tested?</td>
</tr>
<tr>
<td>18. Repeat interviews</td>
<td>Were repeat interviews carried out? If yes, how many?</td>
</tr>
<tr>
<td>19. Audio/visual recording</td>
<td>Did the research use audio or visual recording to collect the data?</td>
</tr>
<tr>
<td>20. Field notes</td>
<td>Were field notes made during and/or after the interview or focus group?</td>
</tr>
<tr>
<td>21. Duration</td>
<td>What was the duration of the interviews or focus group?</td>
</tr>
<tr>
<td>22. Data saturation</td>
<td>Was data saturation discussed?</td>
</tr>
<tr>
<td>23. Transcripts returned</td>
<td>Were transcripts returned to participants for comment and/or correction?</td>
</tr>
</tbody>
</table>

**Domain 3: analysis and findings**

**Data analysis**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>24. Number of data coders</td>
<td>How many data coders coded the data?</td>
</tr>
<tr>
<td>25. Description of the coding tree</td>
<td>Did authors provide a description of the coding tree?</td>
</tr>
<tr>
<td>26. Derivation of themes</td>
<td>Were themes identified in advance or derived from the data?</td>
</tr>
<tr>
<td>27. Software</td>
<td>What software, if applicable, was used to manage the data?</td>
</tr>
<tr>
<td>28. Participant checking</td>
<td>Did participants provide feedback on the findings?</td>
</tr>
</tbody>
</table>

**Reporting**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>29. Quotations presented</td>
<td>Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number</td>
</tr>
<tr>
<td>30. Data and findings consistent</td>
<td>Was there consistency between the data presented and the findings?</td>
</tr>
<tr>
<td>31. Clarity of major themes</td>
<td>Were major themes clearly presented in the findings?</td>
</tr>
<tr>
<td>32. Clarity of minor themes</td>
<td>Is there a description of diverse cases or discussion of minor themes?</td>
</tr>
</tbody>
</table>

Current perspectives on the factors affecting runners’ preferences for footwear

INFORMATION SHEET FOR PARTICIPANTS (Runners)

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

Researchers: Codi Ramsey, Dr. Gisela Sole, Dr. Daniel Ribeiro, Dr. Peter Lamb, Dr. Anne Mündermann

What is the Aim of the Project?

The aim of the project is to find out your perspective of the factors affecting your selection of running footwear. We would like your opinions and beliefs about running shoes and how they may affect your performance and risk for injury. This project is being undertaken as part of the requirements for the PhD thesis of Codi Ramsey. The results will define current trends in factors affecting selection of footwear by runners, and inform teaching and future research studies.

What Types of Participants are being sought?

We are looking for runners from the local community, who regularly run more than 30 km per week, aged 20 to 50 years old, and currently not limited in their training by injuries. Runners are invited to contact Codi Ramsey or any member of the research team if they have any questions about the study, and if they are willing to participate. We would like to include up to twelve participants (maximum six per group) to take part in a focus-group discussion. There will be no reimbursement for participating in the study, but a summary of the results will be made available to participants on completion of the study.
What will Participants be asked to do?

Should you agree to take part in this project, please contact Codi Ramsey to answer any further questions you may have. The focus group discussion will be conducted at the School of Physiotherapy at the University of Otago. The discussion time will be scheduled to accommodate most participants and will maximally 1-hour. If you are unable to attend in-person, you may attend via OtagoConnect (an online communication programme, similar to Skype, allowing electronic recording of the conversation). The discussion will be led by Codi Ramsey (PhD candidate) and another member of the research team may also attend.

The discussion will be audio-taped (digital recorder or OtagoConnect) and the interviewers may make notes in writing. The questions will relate to your perceptions and experience purchasing and running in different shoes. The precise nature of the questions which will be asked has not been determined in advance, but will depend on the way in which the discussion develops. Consequently, although the School of Physiotherapy Ethics Committee is aware of the general areas to be explored in the discussion, the Committee has not been able to review the precise questions to be used. In the event that the line of questioning does develop in such a way that you feel hesitant or uncomfortable you are reminded of your right to decline to answer any particular question(s).

At any time throughout the study you may choose to withdraw from the project without any disadvantage to yourself. However, data cannot be excluded once it has been transcribed.

What Data or Information will be collected and what use will be made of it?

We will ask you to complete a questionnaire for your demographic information (age, sex, ethnicity) and information related to your running experiences and footwear choices. All data collected and recordings will be securely stored in such a way that only those mentioned above will be able to gain access to it. Data obtained as a result of the research will be retained for at least 10 years in secure storage. Any personal information held about the participants [such as contact details, audio tapes after they have been transcribed etc.,] will be destroyed at the completion of the research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

The results of the project will be written up as Ms Ramsey’s PhD thesis and may also be published. It will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity.

Can Participants change their mind and withdraw from the project?

You may withdraw from participation in the project at any time and without any disadvantage to yourself.

What if Participants have any Questions?

If you have any questions about our project, either now or in the future, please feel free to contact either:-
This study has been approved by the School of Physiotherapy. However, if you have any concerns about the ethical conduct of the research you may contact the University of Otago Human Ethics Committee through the Human Ethics Committee Administrator (ph 03 479-8256). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Appendix 9: Bracketing exercise for qualitative inquiry

The increased attention and support of qualitative research is reassuring as the importance of patient feedback and opinions are of greater value in the scientific community. Researchers aim to ensure proper and unbiased translation of the perceptions of their participants through the use of reflexivity or bracketing. This involves acknowledging their own thoughts, feelings and preconceptions prior to conducting qualitative research, as a conscious effort to reduce the incidence of imposing their beliefs into the data. Bracketing is not restricted to a set of rules or guidelines, in many ways this makes the task daunting and complicated. However, Ahern, (1999) suggests ten areas for authors to address when preparing for qualitative research. The areas are divided into subgroups “preparation”, “post-analysis” and “feedback”, all of which are addressed prior to conducting the first interview and should be consulted frequently throughout the qualitative research process. The following is my personal reflexivity toward qualitative research regarding the perceptions and beliefs of physiotherapists and podiatrists in the management and treatment of runners with iliotibial band syndrome and; the factors that influence runners’ choices in footwear.

My personal background in physical education, limits the scope of my clinical knowledge regarding physio/podiatrist procedures, evaluation, and treatment of overuse running injuries. I have only been to a physio once for my own injuries and the only treatment I received was ultrasound and deep tissue massage. I feel that by asking this cohort questions about what they do on a day-to-day basis, I will deepen my understanding of their role in the prevention of overuse injuries. My personal interest of running also piques my interest for conducting this project, as I want to help other runners become educated in ways to prevent injury and maximize their involvement in running. My role in this research is to gather information from practitioners and runners and analyse it in a way that I can help educate both parties on methods that work best when working with injuries.

I value the role prevention rather than rehabilitation and believe it should also be the primary role of physio’s and podiatrists. They are trained and involved in many peoples lives. However, I believe they are under performing in public education of prevention strategies and are focused on rehabilitation. As a runner, I would much rather have a clinic brought to me to evaluate possible mechanics that could result in injury rather than wait to be injured and be in a vulnerable position of pain that I seek out help to get healthy again.

There is an absence of personal or professional conflict with any of the participants of my study. I acknowledge that podiatrists may be hesitant in revealing information to me as I am in the school of physiotherapy. I also acknowledge that physio’s may be reluctant to provide me with information that may contradict what another physio practices. Practitioners may speak in more layman’s terms because my background is not clinical based, however, I will make all attempts to assure them that I understand clinical language and will not be lost in the discussion. I am comfortable with clinicians and believe they have a very delicate job. I find it especially exciting when they consider the role of footwear in their assessment, so I will consciously remind myself before each interview to remain neutral on this topic.

My advisor and her husband are well-known in Dunedin and some physiotherapists do not agree or accept their beliefs. Gisela’s presence will be limited to prevent her interests and beliefs from affecting the other practitioners. I will be aware of this possible conflict and will remain neutral and respectfully redirect any discussion that arises regarding the beliefs or practices of other clinicians.

It is my aim to allow the practitioners to feel like they are educating me and providing me with a robust understanding of what goes on inside a clinic. I aim to allow the runners to speak
freely of their reasons for shoes and express a relationship that I also choose shoes for the same reasons they do: colour, style, hype, etc. As this study is unlikely to reveal any psychological or emotional stress, attention to any discomfort will be addressed by allowing participants to expand on the reasons why certain aspects of the questions are stressful. I will be attuned to my reactions to participants’ responses. When I analyse data, my feelings and thoughts about particular results will be set aside so the data can be revealed in the most objective manner.

I acknowledge that I may become influenced by the act of conducting the interviews and data saturation may not be fulfilled; therefore, I will consult with my supervisors prior to assuming data saturation.

If after the interviews are completed, data saturation is not fulfilled, I will consider gathering more participants for more focus groups or requesting additional information through surveying or further interviews with the prior participants.

During the writing process I will uncover themes that I both agree and disagree with to ensure validity of the results and my openness to the data.

A full literature review will be conducted after the data collection process is complete. The literature will support both sides of the data collected and a neutral approach will be taken to portray the results of the study. The results will be supported by literature to ensure it is evidence based and is more than my self expression.

I acknowledge that the outcomes of the study may be influenced by my own beliefs and that limitations are present when making inferences. The goal of this research is to enhance my own knowledge base as well as support future research directed at physiotherapist’s/podiatrist’s management and treatment of overuse running injuries, as well as the factors that influence runners to choose their footwear.
Appendix 10: Runner interview semi-structured questions

Opening:

- How did you get into running?
- Distance/week?
- Cross training?
- Type of running shoe?
- Shoes for different activities? Casual?
- What do you like about your shoes?
- What do you dislike about your shoes?

Purchasing footwear:

- Say you need a new pair of running shoes...How do you go about finding the right pair?
  - What features of a running shoe are important to you?
- Have you ever bought shoes from a specialty shoe store?
- Why did you choose that particular store?
- What did you like about that store?
  - Listen for gait analysis, shoe fittings, foot analysis, plantar pressure,
    - What did you find out about yourself from these tests?
    - What makes you trust the sales team at that store?
- How many pairs of shoes did you try on before deciding?
- Have you ever bought shoes online?
- Why?
  - How many websites/stores did you browse before deciding?
  - How did you decide that those shoes were the ones you wanted to buy?
  - What did you like about the online buying process?
  - Were you happy when they arrived?
- Why not?
  - What would make your more inclined to buy online?
- How does the media (magazines, ads, commercials) affect your decision making process of buying new shoes? WHY???
  - Influence of minimalist/barefoot trend?
- Have you ever sought advice for footwear from a health professional, such as podiatrist or physiotherapist?
  - How did they go about giving you advice/suggestions?
  - What did you find useful or not useful about their advice?
- What do you like about buying shoes?
- What do you dislike about buying shoes?
- Challenges? Anything you wish would make buying easier?

Replacing footwear

- Do you have any signs or rules for replacing your shoes?
  - Expand
  - Prompt: how often?
  - Alternate between styles/brands?
  - What do you do with old?

Any other info or questions?
Hello! I would like to thank you for participating in this research study and for the information you shared with me. I would like to provide you with a summary of the results and invite you to respond if there is any further aspect you would like to highlight, or if you feel the summary below does not portray your experiences.

Why this study was conducted:

I was interested in exploring the factors that influence uninjured runner’s choices of footwear. We focused on the impact of intrinsic and extrinsic factors on your decision-making processes when choosing your running shoes. A further aim of this study was to identify how runners perceive footwear as a mechanism for injury prevention. This information allows me to understand runner’s perspectives of footwear and possibly identify risk-factors attributed to areas beyond the individual runner.

Results of the study:

Interviews from 12 volunteers were transcribed and analysed.

After analysis of the interview data and discussions within the research team, the following main themes regarding the factors influencing runner’s choices of footwear were defined as: economics, other people, and runner’s own needs.

1. **Economics**

   Price is a concern for most runners. In general, participants want to find the best shoe, at the lowest price. Often times this includes purchasing shoes online or from overseas, which can then lead runners to feel guilty for not supporting the local businesses. However, there is also a concern with the selection and availability of footwear in the local stores. Several runners expressed frustration with not being able to find the desired shoe in town or that the store did not carry the appropriate size.

   When to replace running shoes is arbitrary and confusing and can be costly if runners are logging high distances. Four runners monitor and track the distances for each pair of shoes and replace them after a determined number of kilometres. Other runners use a more intuitive method and buy shoes at signs of injury or when they are no longer comfortable. One runner admitted to wearing shoes to the point that they were falling apart, just to avoid having to buy another pair of shoes.

   Although not a large number of participants discussed humanitarian impacts of footwear, the researchers were surprised by the four participants that expressed the ethical
manufacturing of some brands of footwear influences their shoe choices. Other runners reported donating second-hand footwear to local and international charities for people in need.

2. Other people
The term “fact-finding mission” was used by one participant and is a great summary of how other people seem to impact your choices of footwear. The opinions and knowledge of how a certain shoe has worked for someone else is welcomed information, whether it be from other runners, media, research, sales people or health professionals. Runners have preferences towards whom they receive information from, but generally seek advice when considering buying a new brand/model or style of shoe. From the intrinsic standpoint runners reflect upon past experiences (good and bad) to inform their future shoe purchases.

3. Runner’s own needs
Most participants indicated their footwear choices are related to a spectrum of complex and interrelated characteristics that satisfy their needs for performance and comfort. Runner’s typically have an affinity to specific brands or shoe types. Six participants described buying footwear for the purpose of improving their biomechanics or altering gait patterns. Seven participants use multiple pairs of footwear for specific running activities (e.g. racing, speed-work or terrain).

Runners which seek footwear for specific performance related purposes also are motivated by possible injury prevention benefits from using shoes that meet their needs. It is generally perceived that using the ‘wrong’ footwear can result in injury. This includes footwear that is uncomfortable, despite its claimed effects. One participant was uninfluenced by the possible performance enhancing footwear properties, but just wants to continue to enjoy running.
Appendix 12: Qualitative study information sheet (clinicians)

[Reference Number: D15/375]
[12 November 2015]

Current perspectives on the assessment and prescriptions of footwear for overuse running knee injuries

INFORMATION SHEET FOR PARTICIPANTS
(Physiotherapists/Podiatrists)

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

Researchers: Codi Ramsey, Dr. Gisela Sole, Dr. Daniel Ribeiro, Dr. Peter Lamb, Dr. Anne Mündermann

What is the Aim of the Project?

The aim of the project is to find out your perspectives of current evaluation and management of runners with overuse knee injuries, such as patellofemoral pain or iliotibial band syndrome. Besides the overall management, we would also like to explore what procedures you follow when assessing and prescribing footwear and/or orthotic inserts for such patients. We would like your opinions on current strengths or challenges associated with management of patients with overuse running injuries. This study will determine current trends in clinical practice and inform teaching and future research studies. This project is being undertaken as part of the requirements for the PhD thesis of Codi Ramsey.

What Types of Participants are being sought?

We are looking for physiotherapists and podiatrists who are currently responsible for the rehabilitation management of patients with overuse running injuries of the knee. Practices will be contacted by email and invited to contact the research team if they have any questions about the study. The practice owner and/or employees will be asked to contact the investigators if they are willing to participate. We would like to include 12 practitioners from at least eight different practices to take part in a focus-group discussion. Up to 6 participants will be included in a focus group, if more than three physiotherapists from the same practice volunteer, three
will be selected by the researcher using a random number list. There will be no reimbursement for participating in the study, but a summary of the results will be made available to participants on completion of the study.

What will Participants be asked to do?

Should you agree to take part in this project, you will be asked to contact Codi Ramsey to answer any questions you may have. Up to three colleagues from your practice may participate. The focus group discussion will be conducted at the School of Physiotherapy at the University of Otago. The discussion time will be scheduled to accommodate most participants and will not exceed 1-hour. If you are unable to attend in-person, you may attend via OtagoConnect (an online communication programme, similar to Skype, allowing electronic recording of the conversation). The discussion will be led by Codi Ramsey (PhD candidate) and another member of the research team may also attend.

The discussion will be audio-taped (digital recorder or OtagoConnect) and the interviewers may make notes in writing. The questions relate to your perceptions and experience regarding overall assessment and management of overuse running knee injuries. The precise nature of the questions which will be asked has not been determined in advance, but will depend on the way in which the discussion develops. Consequently, although the School of Physiotherapy Ethics Committee is aware of the general areas to be explored in the discussion, the Committee has not been able to review the precise questions to be used. In the event that the line of questioning does develop in such a way that you feel hesitant or uncomfortable you are reminded of your right to decline to answer any particular question(s). At any time throughout the study you may choose to withdraw from the project without any disadvantage to yourself. However, data cannot be excluded once it has been transcribed.

What Data or Information will be collected and what use will be made of it?

We will ask you to complete a questionnaire for your demographic information (age, sex, ethnicity) and information related to your academic qualification and years of clinical practice. All data collected and recordings will be securely stored in such a way that only those mentioned above will be able to gain access to it. Data obtained as a result of the research will be retained for at least 10 years in secure storage. Any personal information held about the participants [such as contact details, audio tapes after they have been transcribed etc.,] will be destroyed at the completion of the research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

The results of the project will be written up as Ms Ramsey’s PhD thesis and may also be published. It will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity.

Can Participants change their mind and withdraw from the project?
You may withdraw from participation in the project at any time and without any disadvantage to yourself.

What if Participants have any Questions?

If you have any questions about our project, either now or in the future, please feel free to contact either:-

**Codi Ramsey**  
School of Physiotherapy  
Email: Codi.ramsey@otago.ac.nz

**Dr. Gisela Sole**  
School of Physiotherapy  
Email: Gisela.sole@otago.ac.nz

**Dr. Daniel Ribeiro**  
School of Physiotherapy  
Email: daniel.ribeiro@otago.ac.nz

**Dr. Peter Lamb**  
School of Physical Education  
Email: peter.lamb@otago.ac.nz

School of Physiotherapy

Email: clinicalresearch.physio@otago.ac.nz

This study has been approved by the School of Physiotherapy. However, if you have any concerns about the ethical conduct of the research you may contact the University of Otago Human Ethics Committee through the Human Ethics Committee Administrator (ph 03 479-8256). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Appendix 13: Practitioner semi-structured interview questions

Intro:
Opening:
  - Time as physio
  - Where worked? Studied?
  - Type of patients
  - # of runner with knee pain/overuse injuries

Evaluation:
  - Prompt: Scenario of 1st time patient with OUKI
    - Note: most will talk about hip/trunk mechanics
    - Listen for mention of gait/shoes/loading...HOW? WHY?
  - Expand
    - Tell me more about gait/shoes/feet assessments
      - What deficiencies do you identify?
      - What does ideal foot look like?
        - Structurally
        - mechanically
    - You mentioned (foot posture, alignment,) how do you assess/measure/evaluate/interpret this?
    - How do you interpret shoe wear patterns?

Treatment:
  - Physical treatments
    - Listen for: (orthotics, shoes, foot core exercises, gait retraining, taping)
      - What kinds (orthotics —medial/lateral wedges-, shoes, taping) WHY?
      - What are short/long term effects of these methods?
      - Follow up periods? Progression for changes in treatment?
    - Short term/long term care, referrals (podiatrists)
    - Education (training, shoes, terrain, health)
  - Expand:
    - Debate of min vs. BF vs. trad
    - Use of patient feedback/perspective
      - What “paradigm” do most patients follow? (minimal vs traditional)
      - How do you address perceptions/beliefs about what they think is best for them?
    - Psychological well being

Challenges:
  - What challenges/barriers do you have with patients?
    - How do you address ones that don’t seek treatment? Stubborn
    - Compliance
    - Other sources of info (web)
    - Why do these challenges exist?
  - Future research
    - Help clinical management
    - Concepts to be explored from research
Appendix 14: Bland-Altman plots

**Between Rater - HHM1**

<table>
<thead>
<tr>
<th>Difference Between Novice and Expert</th>
<th>Mean Measure (Novice vs Expert)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1.96SD 0.846</td>
<td>25</td>
</tr>
<tr>
<td>0.330</td>
<td>30</td>
</tr>
<tr>
<td>-1.96SD -0.186</td>
<td>35</td>
</tr>
</tbody>
</table>

**Between Rater - HHM2**

<table>
<thead>
<tr>
<th>Difference Between Novice and Expert</th>
<th>Mean Measure (Novice vs Expert)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1.96SD 0.704</td>
<td>24</td>
</tr>
<tr>
<td>0.360</td>
<td>28</td>
</tr>
<tr>
<td>-1.96SD 0.016</td>
<td>32</td>
</tr>
</tbody>
</table>
### Appendix 15: STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| **Title and abstract** | 1  
(a) Indicate the study’s design with a commonly used term in the title or the abstract  
(b) Provide in the abstract an informative and balanced summary of what was done and what was found |
| **Introduction** | 2  
Background/rationale | Explain the scientific background and rationale for the investigation being reported |
| | Objectives | State specific objectives, including any prespecified hypotheses |
| **Methods** | 3  
Study design | Present key elements of study design early in the paper |
| | Setting | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection |
| | Participants | (a) Give the eligibility criteria, and the sources and methods of selection of participants |
| | Variables | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable |
| | Data sources/measurement | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group |
| | Bias | Describe any efforts to address potential sources of bias |
| | Study size | Explain how the study size was arrived at |
| | Quantitative variables | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why |
| | Statistical methods | (a) Describe all statistical methods, including those used to control for confounding  
(b) Describe any methods used to examine subgroups and interactions  
(c) Explain how missing data were addressed  
(d) If applicable, describe analytical methods taking account of sampling strategy  
(e) Describe any sensitivity analyses |
| **Results** | 13*  
Participants | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed  
(b) Give reasons for non-participation at each stage  
(c) Consider use of a flow diagram |
| | Descriptive data | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders  
(b) Indicate number of participants with missing data for each variable of interest |
| | Outcome data | 15* Report numbers of outcome events or summary measures |
| | Main results | 16  
(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included  
(b) Report category boundaries when continuous variables were categorized  
(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period |
| | Other analyses | 17 Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses |
**Discussion**

| Key results | 18 | Summarise key results with reference to study objectives |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results |

**Other information**

| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based |

*Give information separately for exposed and unexposed groups.*

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.
Appendix 16: University of Otago ethics approval for feasibility study

Dr D Ribeiro  
School of Physiotherapy

30 August 2017

Dear Dr Ribeiro,

I am again writing to you concerning your proposal entitled "The role of footwear asymmetry on overuse running-related injuries: a prospective feasibility study", Ethics Committee reference number H17/026.

Thank you to Codi Ramsey, PhD student investigator on the above project, for the request for amendment of 20th August 2017 notifying the Committee of additional questions to be added to the exit survey.

The Committee accepts and approves the amendment and thanks you for providing the revised documentation.

Your proposal continues to be fully approved by the Human Ethics Committee. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing. I hope all goes well for you with your upcoming research.

Yours sincerely,

[Signature]

Mr Gary Witte  
Manager, Academic Committees  
Tel: 479 8256  
Email: gary.witte@otago.ac.nz

c.c. Professor I. A Hale  
Dean  
School of Physiotherapy
Title: The role of footwear asymmetry on overuse running-related injuries: a prospective feasibility study

Primary Investigator: Dr Daniel Ribeiro
Secondary Investigator: Dr Peter Lamb
Student Investigator: Ms Codi Ramsey

Concise description of the research
Overuse injuries are common among runners, often resulting in interruptions to regular exercise habits and daily life. Causes of overuse injuries have been explored, including previous injury, muscle strength and mobility, training errors, and biomechanics. However, results have been inconclusive and fail to make definitive cases for factors contributing to overuse injuries in runners. Running shoes differ in terms of their midsole hardness, weight, sole thickness and heel drop. A current trend towards the use of minimalist shoes (low weight, midsole thickness less than 15 mm and less than 7 mm heel drop, and absent stiff arch support) has spiked the interest of runners and researchers. However, most studies investigating overuse running-related injuries have not considered the role of the shoe condition as a risk factor for injury. A recent study from our laboratory speculated that asymmetric changes (wear patterns) of the shoe associated with use over time may contribute towards development of injuries. Inconclusive data is present at this time on the incipience of running related injuries stemming from, or associated with shoe asymmetric wear patterns.

Aims and Outcomes
The aim of this study is to assess the feasibility of a prospective, observational cohort study to assess the role of footwear asymmetry on lower limb overuse injuries among runners. The primary objectives are to: (1) demonstrate the feasibility of recruiting and following-up measurements on novice and recreational runners aged 18-55 years, in Dunedin, New Zealand, who can run at least 20 consecutive minutes and have previously not run more than one half-marathon; (2) estimate the drop-out rate of runners who are selected to participate in the study; (3) identify logistical and/or equipment issues that will refine the protocol for the fully-powered study. The secondary objective is to: (4) obtain estimates of shoe degradation on lower-limb overuse injuries, and standard deviations and correlation coefficients of analysed variables, so that we can estimate the sample size of the full trial.

Interest to Maori
Overuse injuries are common in the general population, including Maori. As these injuries normally are not associated with a specific accident, they are often not covered by ACC. Therefore, these people may not always be able to access to appropriate care. There is some evidence that these overuse injuries, for example of the knee cap (patella-femoral pain syndrome), may have increased risk for future osteoarthritis. Thus, timely and appropriate management of the overuse injuries is critical for future health and continued physical activity. Determining the role of footwear degradation patterns on the incidence and prevalence of overuse injuries in runners will be important to monitoring potential risk factors. Furthermore, the feasibility study will increase understanding of the potential role of footwear in the prevention of these injuries and hopefully will provide clinical suggestions for cost-effective interventions.
Are you a new runner?

This research project aims to assess the relationship between running shoes and overuse injuries in beginner-level runners.

We are seeking male and female participants (aged 18–55) in Dunedin, New Zealand who can run at least 20 consecutive minutes and have previously not run more than one half-marathon. Our aim is to recruit 35 participants.

You will follow a customised gradual-training programme leading up to the Cadbury Half Marathon on September 10, 2017. Footwear will be assessed at baseline, week-3, week-6, week-9 and week-12.

No financial reward will be provided to participants who decide to take part in the study.

Time commitment required: 12-weeks

To find more about participating in the study:
Email: codi.ramsey@otago.ac.nz
or go to otago.ac.nz/running-study

Contact details:
Primary Researcher: Dr Daniel Ribeiro
Email: daniel.ribeiro@otago.ac.nz
PhD Candidate: Codi Ramsey
Tel: 03 479 5422
Email: codi.ramsey@otago.ac.nz

This project has been approved by the University of Otago Human Ethics Committee, (Health). Reference: H17/026.
Appendix 19: Standardised 12-week half-marathon training program

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>Intervals 3x1000</td>
<td>XT</td>
<td>Tempo Run</td>
<td>4k</td>
<td>Rest</td>
<td>XT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3k</td>
<td>Rest or XT</td>
<td>6k</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
<td></td>
<td>Online training log</td>
</tr>
<tr>
<td>Jun-26</td>
<td>Jun-27</td>
<td>Jun-28</td>
<td>Jun-29</td>
<td>Jun-30</td>
<td>Jul-01</td>
<td>Jul-02</td>
</tr>
<tr>
<td>Week 2</td>
<td>Intervals 6x800</td>
<td>XT</td>
<td>5k</td>
<td>Rest or XT</td>
<td>6k</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
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<td>Online training log</td>
</tr>
<tr>
<td>Jul-03</td>
<td>Jul-04</td>
<td>Jul-05</td>
<td>Jul-06</td>
<td>Jul-07</td>
<td>Jul-08</td>
<td>Jul-09</td>
</tr>
<tr>
<td>Week 3</td>
<td>Intervals 3x1000</td>
<td>XT</td>
<td>9 FastGlobal</td>
<td>6k</td>
<td>Rest or XT</td>
<td>7k</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>run, 6k slow</td>
<td>walk</td>
<td>Rest</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jul-10</td>
<td>Jul-11</td>
<td>Jul-12</td>
<td>Jul-13</td>
<td>Jul-14</td>
<td>Jul-15</td>
<td>Jul-16</td>
</tr>
<tr>
<td>Week 4</td>
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<td>XT</td>
<td>5k</td>
<td>Rest or XT</td>
<td>9k</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
<td></td>
<td>Online training log</td>
</tr>
<tr>
<td>Week 5</td>
<td>Intervals 5x1000</td>
<td>XT</td>
<td>Tempo Run</td>
<td>5k</td>
<td>Rest or XT</td>
<td>10k</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3k</td>
<td>Rest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 6</td>
<td>Intervals 7x800</td>
<td>XT</td>
<td>5k</td>
<td>Rest or XT</td>
<td>11k</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7k</td>
<td>Rest</td>
<td></td>
<td>Online training log</td>
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<tr>
<td>Jul-31</td>
<td>Aug-01</td>
<td>Aug-02</td>
<td>Aug-03</td>
<td>Aug-04</td>
<td>Aug-05</td>
<td>Aug-06</td>
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<td>Week 7</td>
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<td>5 FastGlobal</td>
<td>6k</td>
<td>Rest</td>
<td>XT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>run, 6k slow</td>
<td>jog</td>
<td>Rest</td>
<td>Complete</td>
</tr>
<tr>
<td>Aug-07</td>
<td>Aug-08</td>
<td>Aug-09</td>
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<td>Aug-11</td>
<td>Aug-12</td>
<td>Aug-13</td>
</tr>
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<td>Week 8</td>
<td>Intervals 4x600</td>
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<td>5k</td>
<td>Rest or XT</td>
<td>10k</td>
<td>Complete</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
<td></td>
<td>Online training log</td>
</tr>
<tr>
<td>Week 9</td>
<td>Jk</td>
<td>XT</td>
<td>Tempo Run</td>
<td>6k</td>
<td>Rest or XT</td>
<td>12k</td>
</tr>
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<td>9k</td>
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</tr>
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<td>Rest or XT</td>
<td>20k</td>
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<td></td>
<td>6k</td>
<td>Rest</td>
<td></td>
<td>Online training log</td>
</tr>
<tr>
<td>Aug-28</td>
<td>Aug-29</td>
<td>Aug-30</td>
<td>Aug-31</td>
<td>Sep-01</td>
<td>Sep-02</td>
<td>Sep-03</td>
</tr>
<tr>
<td>Week 11</td>
<td>Jk</td>
<td>XT</td>
<td>Tempo Run</td>
<td>5k</td>
<td>Rest or XT</td>
<td>6k</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7k</td>
<td>Rest</td>
<td></td>
<td>Complete</td>
</tr>
<tr>
<td>Sep-04</td>
<td>Sep-05</td>
<td>Sep-06</td>
<td>Sep-07</td>
<td>Sep-08</td>
<td>Sep-09</td>
<td>Sep-10</td>
</tr>
<tr>
<td>Week 12</td>
<td>Intervals 6x400</td>
<td>XT</td>
<td>Rest</td>
<td>Rest or XT</td>
<td>13k</td>
<td>REST</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rest</td>
<td></td>
<td>21k</td>
</tr>
</tbody>
</table>

Footwear assessments:
PARTICIPANT INFORMATION SHEET

[University of Otago’s Human Ethics Committee Reference Number: H17/026]
[17/3/2017]

THE ROLE OF FOOTWEAR ASYMMETRY ON OVERUSE RUNNING-RELATED INJURIES:

A PROSPECTIVE FEASIBILITY STUDY

INFORMATION SHEET FOR PARTICIPANTS

Thank you for showing interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

What is the Aim of the Project?

We would like to know if there is a relationship between footwear degradation patterns and overuse running-related injuries in novice runners. Overuse injuries are injuries which occur in muscle or joints due to repeated stress over time. Footwear is an essential piece of running equipment, yet we are unsure if it is capable of preventing overuse injuries. This project is PhD research for Codi Ramsey.

Expected time involved:

12 weeks (June 18, 2017 – September 10, 2017)

What Type of Participants are being sought?

We are seeking male and female participants (aged 18 – 55) in Dunedin, New Zealand who can run at least 20 consecutive minutes and have previously not run more than one half-marathon. Novice runners will be recruited from the local community to participate in this study. Recruitment adverts will be placed at local running club-houses, specialty running stores, gyms/fitness facilities, as well as social media (Facebook and Twitter).

Participants are excluded if they:
1. Have previous lower-limb (lower back, hip, knee, ankle, foot) injuries that required surgery
2. Are currently training more than five (5) days per week
3. Have previously run more than one half-marathon or longer distance
4. Are unwilling/unable to register for the 2017 Dunedin Cadbury Half-Marathon

By participating in this study, you will be contributing to the body of knowledge surrounding the usefulness of evaluating footwear asymmetry in novice runners.

What will participants be asked to do?
Should you meet the criteria and agree to participate in the study, you will be asked to:

1. **Attend an initial session at the School of Physiotherapy which will take no more than 45 minutes.** At this session, we will:
   a. Determine if you are eligible using the inclusion and exclusion criteria.
   b. Ask you to read the information sheet and sign the consent form if you wish to participate.
   c. Ask you to complete a baseline questionnaire during which will ask questions relating to your demographics (for example: your age, sex, current activity levels, history of prior injuries) and contact information; you will also fill out a questionnaire regarding your current levels of discomfort, pain, or injury.
   d. Perform basic anthropometric measurements (height, weight) and assess your foot type using the Foot Posture Index.
   e. If you choose to participate, we will assess the comfort and total asymmetry of your self-selected running shoes. We will also assess your strike pattern through video assessment while running on a treadmill which will be categorized as: rearfoot, midfoot or forefoot. You will be required to provide a pair of self-selected running shoes.

2. **During the study, you will be asked:**
   a. Wear the same pair of self-selected running shoes for each training session throughout the duration of the study.
   b. Only wear your self-select running shoes for training purposes.
   c. Follow a 12-week (June-September, 2017) standardized training program. The program gradually increases weekly distance (≤ 10% increase from previous week) and includes a variety of training runs 4 times per week with 1-2 days of cross training (any activity other than running) and 1-2 days of rest.
   d. Complete a weekly online questionnaire which will record your levels of discomfort, pain or injury from the prior week of training; this will take no more than 10 minutes to complete.
   e. Attend three footwear measurement sessions at the School of Physiotherapy during training weeks 3, 6, 9, and 12 (July 3-9; July 24-30; August 14-20 and September 3-10, respectively). The same pair of shoes must be evaluated throughout the study.

Please be aware that you may decide not to take part in the project without any disadvantage to yourself of any kind.

**What are the possible risks to you for participating?**

While no major risks are associated with this study, participation in running exercise programs exposes participants to potentially mild musculoskeletal and/or cardiovascular discomfort.

**What Data or Information will be Collected and What Use will be Made of it?**

We will collect the following information:

- Your name and date of birth; email address; phone number; weight; height.
- Your fitness level, running style, foot-type, and past injuries.
- Your current reports of pain, discomfort, or injury in your lower-limbs.
- Your weekly ratings of pain or discomfort during the previous weeks training sessions.
- Your footwear asymmetry and comfort scores.

The researchers will take great care to ensure that your health information is kept confidential at all times. The data from this study will be used in a postgraduate thesis and may be used for publication in the sport injury literature. Every attempt to protect your anonymity will be made by using a randomly-generated personal identification number in place of your name or any other identifiable information. All identification codes associated with your personal information will be kept on an encrypted computer.
All data will be securely stored and accessed by only Dr Daniel Ribeiro, Dr Peter Lamb and Ms. Codi Ramsey and a designated Research Assistant. Any personal information held about the participants (such as contact details) will be destroyed at the completion of the research expect as required by the University of Otago’s research policy. All other data will be encrypted and then stored on password-protected servers. Any hard copy data will be stored in locked cabinets for 10 years after the project and discarded thereafter by an archive officer according to University of Otago’s research policy. At the start of the study, you will have an opportunity to request to view the results. Results will be available to you starting December 2017. The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity during data collection, analysis, and storage.

What are your rights as a participant of the study?

You may withdraw from participation in the project at any time without any disadvantage to yourself of any kind.

What if participants have further questions?

If you have any additional questions about participation our project, either now or in the future, please feel free to contact either:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Daniel Ribeiro</td>
<td>Centre for Health, Activity, and Rehabilitation Research&lt;br&gt;School of Physiotherapy&lt;br&gt;University of Otago</td>
<td>Tel (NZ): +64 3 479 7455&lt;br&gt;<a href="mailto:daniel.ribeiro@otago.ac.nz">daniel.ribeiro@otago.ac.nz</a></td>
</tr>
<tr>
<td>Codi Ramsey</td>
<td>PhD candidate, student researcher&lt;br&gt;Centre for Health, Activity, and Rehabilitation Research&lt;br&gt;School of Physiotherapy&lt;br&gt;University of Otago</td>
<td>Tel (NZ): +64 3 479 5422&lt;br&gt;<a href="mailto:codi.ramsey@otago.ac.nz">codi.ramsey@otago.ac.nz</a></td>
</tr>
</tbody>
</table>

This study has been approved by the University of Otago Human Ethics Committee. If you have any concerns about the ethical conduct of the research you may contact the University of Otago Human Ethics Committee through the Human Ethics Committee Administrator (ph +64 3 479 8256 or gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcomes.
Appendix 21: Data exploration using one-way ANOVA

This one-way ANOVA was conducted to gain a better understanding of the change in TAS overtime. This analysis helped the PhD candidate to further understand the effects of TAS on RRI. This also served as a research training exercise to gain knowledge on a different statistical analysis. Table 11.1 indicates there are two time-points with significant differences (pain side Total TAS baseline vs week 12; non-pain side Total TAS baseline vs week 6), however these differences appear to be random. No significant differences in means for any other measurements were observed for the pain side TAS scores (Table 11.1), non-pain side TAS scores (Table 11.2) and comfort scores (table 11.3). Some comparisons could not be computed in the statistical software due to the standard error of the differences being 0.

No significant effects of time were found, $F(1, 82.18) = 2.87, p=0.09$. These results were similar when considering the quadratic $F(1, 81.80) = 0.97, p=0.33$ and cubic $F(1, 82.18) = 0.58, p=0.45$ effects of time, and only slight changes to the log likelihood were observed: $time^2 (-2LL = 634.84)$ and $time^3 (-2LL = 634.26)$, indicating time is not a factor on the pain severity scores among the cohort in this study.
Table 11.1: Within-subject differences of TAS means between time-points

<table>
<thead>
<tr>
<th>Pain-side</th>
<th>Week 3 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 6 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 9 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 12 Mean difference (SD)</th>
<th>CI 95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total TAS</td>
<td>1.67 (2.66) mm</td>
<td>-1.12 – 4.46</td>
<td>2.00 (2.34) mm</td>
<td>-0.91 – 4.91</td>
<td>0.75 (2.06) mm</td>
<td>-2.53 – 4.03</td>
<td>2.33 (0.58) mm</td>
<td>0.90 – 3.77</td>
</tr>
<tr>
<td>RF TAS</td>
<td>0.25 (0.50) mm</td>
<td>-0.55 – 1.05</td>
<td>NA</td>
<td>NA</td>
<td>-1.00 (1.41) mm</td>
<td>13.71 – 11.71</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>FF TAS</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
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<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Week 3</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Total TAS</td>
<td>-0.94 (2.94) mm</td>
<td>-2.41 – 0.52</td>
<td>-1.53 (3.24) mm</td>
<td>-3.12 – 0.14</td>
<td>-0.78 (1.30) mm</td>
<td>-1.78 – 0.22</td>
<td>-0.47 (2.62) mm</td>
<td>-1.915 – 0.98</td>
</tr>
<tr>
<td>RF TAS</td>
<td>-1.10 (1.79) mm</td>
<td>-2.38 – 0.18</td>
<td>-0.70 (1.70) mm</td>
<td>-1.91 – 0.52</td>
<td>-0.78 (1.30) mm</td>
<td>-1.78 – 0.22</td>
<td>-0.66 (1.41) mm</td>
<td>-0.66 – 0.41</td>
</tr>
<tr>
<td>FF TAS</td>
<td>-0.70 (2.11) mm</td>
<td>-2.21 – 0.81</td>
<td>0.30 (0.95) mm</td>
<td>-0.38 – 0.98</td>
<td>0.22 (1.20) mm</td>
<td>-0.70 – 1.15</td>
<td>-0.31 (2.13) mm</td>
<td>0.02 – 0.39</td>
</tr>
<tr>
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<tr>
<td>Total TAS</td>
<td>-0.65 (2.96) mm</td>
<td>-2.17 – 0.87</td>
<td>0.13 (2.13) mm</td>
<td>-1.05 – 1.32</td>
<td>-0.13 (0.64) mm</td>
<td>-0.66 – 0.41</td>
<td>1.00 (1.93) mm</td>
<td>-0.61 – 2.61</td>
</tr>
<tr>
<td>RF TAS</td>
<td>-0.33 (1.80) mm</td>
<td>-0.66 – 0.41</td>
<td>-0.13 (0.64) mm</td>
<td>-0.66 – 0.41</td>
<td>-0.66 (1.41) mm</td>
<td>-0.66 – 0.41</td>
<td>1.00 (1.93) mm</td>
<td>-0.61 – 2.61</td>
</tr>
<tr>
<td>FF TAS</td>
<td>1.22 (1.72) mm</td>
<td>-0.97 – 2.54</td>
<td>0.70 (2.07) mm</td>
<td>-0.68 – 1.61</td>
<td>-0.10 (1.85) mm</td>
<td>-1.43 – 1.23</td>
<td>-0.10 (0.57) mm</td>
<td>-0.51 – 0.31</td>
</tr>
</tbody>
</table>

NA: T-tests could not be computed because the standard error of the difference is 0

Bold text indicates statistically significant difference in means (p <0.05)
Table 11.2: Within participant differences between TAS means of non-pain side at five time-points

<table>
<thead>
<tr>
<th>Non-pain side</th>
<th>Week 3</th>
<th></th>
<th>Week 6</th>
<th></th>
<th>Week 9</th>
<th></th>
<th>Week 12</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Mean difference (SD)</td>
<td>CI 95%</td>
<td>Mean (SD)</td>
<td>CI 95%</td>
<td>Mean difference (SD)</td>
<td>CI 95%</td>
<td>Mean difference (SD)</td>
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<td><strong>Baseline</strong></td>
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<td></td>
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<tr>
<td>Total TAS</td>
<td>0.05 (2.35) mm</td>
<td>-1.96 – 2.96</td>
<td>1.00 (0.71) mm</td>
<td><strong>0.12 -1.88</strong></td>
<td>-1.50 (1.92) mm</td>
<td>-4.55 – 1.55</td>
<td>1.67 (1.15) mm</td>
<td>-1.20 – 4.54</td>
</tr>
<tr>
<td>RF TAS</td>
<td>1.33 (2.16) mm</td>
<td>-0.93 – 3.60</td>
<td>0.00 (0.82) mm</td>
<td>-1.30 – 1.30</td>
<td>-0.25 (0.50) mm</td>
<td>-1.05 – 0.55</td>
<td>-0.75 (0.96) mm</td>
<td>-2.27 – 0.77</td>
</tr>
<tr>
<td>FF TAS</td>
<td>-0.50 (1.38) mm</td>
<td>-1.95 – 0.95</td>
<td>0.50 (2.65) mm</td>
<td>-3.71 – 4.71</td>
<td>0.50 (2.38) mm</td>
<td>-3.29 – 4.29</td>
<td>-0.25 (2.22) mm</td>
<td>-3.78 – 3.28</td>
</tr>
<tr>
<td><strong>Week 3</strong></td>
<td></td>
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</tr>
<tr>
<td>Total TAS</td>
<td>-0.50 (2.66) mm</td>
<td>-1.82 – 0.82</td>
<td>-0.65 (3.12) mm</td>
<td>-2.25 – 0.96</td>
<td>-0.13 (2.42) mm</td>
<td>-1.47 – 1.21</td>
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</tr>
<tr>
<td>RF TAS</td>
<td>0.33 (1.12) mm</td>
<td>-2.27 – 0.77</td>
<td>-0.20 (1.23) mm</td>
<td>-10.8 – 0.68</td>
<td>-0.11 (1.05) mm</td>
<td>-0.92 – 0.70</td>
<td>0.11 (0.93) mm</td>
<td>-0.60 – 0.82</td>
</tr>
<tr>
<td>FF TAS</td>
<td>0.22 (1.20) mm</td>
<td>-0.70 – 1.15</td>
<td>-0.30 (2.21) mm</td>
<td>-1.88 – 1.28</td>
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</tr>
<tr>
<td><strong>Week 6</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total TAS</td>
<td>-0.29 (2.02) mm</td>
<td>-1.34 – 0.75</td>
<td>-0.20 (1.86) mm</td>
<td>-1.23 – 0.83</td>
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<tr>
<td>RF TAS</td>
<td>-0.20 (0.92) mm</td>
<td>-0.86 – 0.46</td>
<td>-0.50 (0.76) mm</td>
<td>-1.13 – 0.13</td>
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</tr>
<tr>
<td>FF TAS</td>
<td>-0.50 (2.07) mm</td>
<td>-1.98 – 0.98</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Week 9</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total TAS</td>
<td>-0.67 (2.43) mm</td>
<td>-1.42 – 1.28</td>
<td></td>
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</tr>
<tr>
<td>RF TAS</td>
<td>-0.10 (0.99) mm</td>
<td>-0.81 – 6.11</td>
<td></td>
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</tr>
<tr>
<td>FF TAS</td>
<td>-0.20 (1.23) mm</td>
<td>-1.08 – 0.68</td>
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</table>

Bold text indicates statistically significant difference in means (p <0.05)
Table 11.3: Differences between footwear comfort means at five time-points

<table>
<thead>
<tr>
<th></th>
<th>Week 3 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 6 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 9 Mean difference (SD)</th>
<th>CI 95%</th>
<th>Week 12 Mean difference (SD)</th>
<th>CI 95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>Comfort</td>
<td>-0.51 (11.91) au</td>
<td>-5.93 – 4.91</td>
<td>-0.76 (8.35) au</td>
<td>-4.78 – 3.26</td>
<td>1.54 (9.95) au</td>
<td>-3.25 – 6.34</td>
<td>3.11 (9.90) au</td>
</tr>
<tr>
<td>Week 3</td>
<td>Comfort</td>
<td>1.47 (7.87) au</td>
<td>2.45 – 5.38</td>
<td>3.15 (7.67) au</td>
<td>-0.66 – 6.97</td>
<td>4.67 (9.89) au</td>
<td>-0.80 – 10.15</td>
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</tr>
<tr>
<td>Week 6</td>
<td>Comfort</td>
<td>2.30 (7.22) au</td>
<td>-1.18 – 5.79</td>
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<td>2.79 (7.03) au</td>
<td>-1.10 – 6.69</td>
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<tr>
<td>Week 9</td>
<td>Comfort</td>
<td></td>
<td></td>
<td>1.16 (6.30) au</td>
<td>-2.33 – 4.64</td>
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</table>

au: arbitrary units
### Appendix 22: TAS scores of participant footwear

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<th>Forefoot Asymmetry</th>
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<td>Right Shoe</td>
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<td>Left shoe</td>
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*au = arbitrary units of comfort scores*