The effect of integrating micro spring technology into running shoes to influence biomechanical parameters and knee pain/comfort scores in recreational runners with knee pain

by

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STUDENT DECLARATION

I declare that while registered as a candidate for the research degree, I have not been a registered candidate or enrolled student for another award of the University or other academic or professional institution.

I declare that no material contained in the thesis has been used in any other submission for an academic award and is solely my own work.

Signature of Candidate:

Type of Award:	Doctor of Philosophy
School:	School of Health Sciences

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ABSTRACT

The continued popularity of recreational running and an ever-increasing focus on injury prevention and pain reduction has led to a significant recent expansion in the sports technology market. Many new technologies put forward claims around reducing the risk of injury, but very few offer detailed supporting evidence to substantiate these claims. As injury levels in recreational runners remain high it would seem the technologies currently used in running shoes are not effectively addressing this problem. This thesis focused on exploring the potential of a new and unique pocketed micro spring technology to influence biomechanical and clinical measures in a multi-faceted interdisciplinary investigation.

The two main aims of this piece of work were to identify whether pocketed micro spring technology could be viably and effectively integrated into a commercial branded running shoe and to explore the efficacy and effectiveness of such technology on recreational runners with and without knee pain.

Firstly, an iterative process was followed to establish the most effective mass-spring-damper solution that could be created with the resources available and that was also technically feasible to mass produce. This stage of the research comprised of a number of small studies exploring the effect of pocketed micro spring technology on impact loading rates in a laboratory-based setting using primarily kinetic analysis. In total 35 healthy recreational runners were tested through the iteration process. During detailed analysis of human trials, important biomechanical variances were highlighted specifically within the first 5% of stance phase, leading to a more detailed exploration of the instantaneous loading rate principle than has been outlined in previous published literature.

Work also included technical modifications to the technology itself in an attempt to engineer a performance driven solution capable of improving the shock absorption characteristics exhibited by running shoes currently on the market. From the impact data of the healthy subjects, key loading parameters which reflected the mechanics of foot impacts during running were used to develop a new drop rig testing machine. Although not an original aim of this thesis, this development was seen as an opportunity to attempt to eliminate the intra and inter subject variability of human running trials. This machine aimed to replicate both rearfoot and forefoot impact loading during running to determine the effects of subtle

differences in the design and materials used in running shoes. Results from these studies established that it was possible to develop a pocketed micro spring capable of reducing initial vertical loading rates, more effectively than popular branded market leading running shoe technology.

Once a running shoe with a mass-spring-damper system in the midsole capable of reducing impact forces experienced when running had been developed, a second phase larger study was carried out to examine the influence of pocketed micro spring technology on biomechanical parameters, and pain and comfort scores, in recreational runners with and without knee pain. As part of this study, the runners took part in outdoor running trials in both their regular running shoes and running shoes integrating pocketed micro spring technology. Inertial Measurement Units or IMUs (Delsys inc) were used to measure biomechanical variables and Numeric Comfort Rating Scale (NCRS) questionnaires were used to collect comfort data from both groups. The IMUs allowed this study to investigate angular velocity parameters alongside deceleration parameters to explore impact loading and stability during initial foot contact, also enabling the use of such data as proxy measures to the force plates used in the first stage of this research. Knee Injury and Osteoarthritis Outcome Score (KOOS) and Numeric Pain Rating Scale (NPRS) questionnaires were also used to collect pain data from those individuals knee pain.

Results demonstrated clear and significant reductions in both vertical impact jerk and internal tibial rotation velocity in both participant groups when wearing the new technology, this included 16.0% (knee pain group) and 11.7% (healthy group) reductions respectively for vertical impact jerk, and 19.1% (knee pain group) and 32.6% (healthy group) reductions respectively for internal tibial rotation velocity. Grouped and individual analysis showed a strong link between biomechanical changes and comfort, with the recreational runners with knee pain experiencing lower levels of pain and greater levels of comfort when wearing and training in the shoes with the pocketed micro spring technology.

This thesis has provided information not previously available regarding the enhancement and integration of a mass-spring-damper system into a running shoe. This work offers a unique and novel insight into the potential of pocketed micro spring technology to reduce key biomechanical parameters, increase comfort and reduce pain across healthy and knee pain recreational runners.

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GLOSSARY OF ABBREVIATIONS AND DEFINITIONS

2-D – Two dimensional

3-D – Three dimensional

ADL – Activities of Daily Living

AKPS – Anterior Knee Pain Scale

AMSMC - Allan McGavin Sports Medicine Clinic

AMTI - Advanced Mechanical Technology Inc

ANOVA – Analysis of variance

ASCII – American Standard Code for Information Interchange

ASTM – American Society for Testing and Materials

AVLR – Average Vertical Loading Rate

BBC – British Broadcasting Corporation

BMJ – British Medical Journal

BS – British Standard

BW – Body Weights

BW/s – Body weights per second

C3D – Document format specific to C-Motion (Visual 3-D)

CAST – Calibrated Anatomical Systems Technique

CINAHL - Cumulative Index to Nursing and Allied Health Literature

CNC – Computer Numeric Control

DNA - Deoxyribonucleic Acid

EVA - Ethylene Vinyl Acetate

GRF – Ground Reaction Force

Hz – Hertz, a measure of frequency

IKDC - International Knee Documentation Committee

IBM – International Business Machines

IC – International Corporation

ICF – International Classification of Functioning, Disability and Health

IEC - International Electrotechnical Commission

IMU – Inertial Measurement Unit

ISO - International Organization for Standardization

IST – Institute of Spring Technology

ITBS - Iliotibial band syndrome

IVLR – Instantaneous Vertical Loading Rate

Kg - Kilogram

km/h – Kilometres per hour

KMT - Knight Mechanical Testing

KNEST – Knee Pain Screening Tool

KOOS - Knee injury and osteoarthritis outcome score

KTP – Knowledge Transfer Partnership

MIC - Minimal Important Change

MID – Minimum Important Difference

mm - Millimetres

m/s – Metres per second

N – Newton, a unit of force

N/mm – Newtons per millimetre

NCBI - National Centre for Biotechnology Information

NCRS – Numeric Comfort Rating Scale

NPRS – Numeric Pain Rating Scale

PFP – Patellofemoral Pain

PU – Polyurethane

QOL – Quality of Life

QTM – Qualisys Track Manager

ROM – Range of Motion

RUVID - Red de Universidades Valencianas para el fomento de la Investigación

SD – Standard Deviation

SI - International System of Units

SMS INC - Sports Marketing Surveys Inc

SPM – Statistical Parametric Mapping

SPSS – Statistical Package for the Social Sciences

STEMH - Science, Technology, Engineering, Medicine and Health

SQSE - Satisfaction with the quality of the sporting experience

UCLan – University of Central Lancashire

UK – United Kingdom

UKAS – United Kingdom Accreditation Service

USA – United States of America

VALR – Vertical Average Loading Rate

VAS – Visual Analogue Scale

VILR – Vertical Instantaneous Loading Rate

CHAPTER 1: INTRODUCTION

1.1 Overview

Recent results of international participation research suggest that the UK's recreational running population has reached in excess of 10.5 million runners with a trend towards increased participation year on year (SMS INC, 2014). For many running represents a cost effective and convenient way to stay fit and healthy. Unfortunately, however, studies into the prevalence of running injuries suggest that overuse injuries are a common problem for both recreational and competitive runners (Hreljac, 2004), with approximately 66% of runners each year experiencing a pathology related to running (Messier et al, 2018).

This research work aimed to explore the potential of micro spring technology to influence biomechanical factors thought to contribute to running injuries, specifically knee injuries. The thesis also aims to provide runners, researchers and footwear manufacturers with new knowledge regarding the link between biomechanical parameters and clinical outcome measures, with respect to running injuries.

The knee is regularly cited as the most common site of running injury and as such was the focus of the following investigations. In a study of 2002 patients examined at the Allan McGavin Sports Medicine Clinic (AMSMC), 42.1% of the total injuries assessed in runners were presented at the knee. Other common sites were the foot/ankle (16.9%), lower leg (12.8%), hip/pelvis (10.9%), Achilles/calf (6.4%), upper leg (5.2%), and lower back (3.4%). (Taunton et al, 2002). The studies outlined in this thesis are focused primarily upon kinetic rather kinematic biomechanical outcome measures, namely loading rate and jerk, as a significant proportion of the existing research literature has explored a wide variety of kinematic measures associated to knee injuries in recreational runners with little consensus as to the most clinically important kinematic measure.

Therefore, the literature review of this thesis focused on the role that impact loading plays in running injuries, which is widely acknowledged as an important area of interest when exploring the aetiology of a number of injuries, particularly in relation to the knee. To date research literature has established that peak ground reaction force (GRF) during impact on its own is not an indicator of injury risk and that perhaps the rate of loading at impact gives a better insight into propensity to cause problems. The majority of studies that have investigated loading rate have focused on average vertical loading rate, defined as the slope of the line through the 20% point and the 80% point up to the peak impact point on the runner's GRF profile. However, more recent studies, including Crowell and Davis (2011), have begun to consider the instantaneous vertical loading rate, defined as the maximum slope of the vertical ground reaction force curve between successive time points in the region from 20% of the vertical impact peak to 80% of the vertical impact peak. During the process of establishing whether micro spring technology could influence biomechanical factors thought to contribute to knee related running injuries, this thesis explored this concept in even greater detail by analysing vertical loading rate values specifically within the first 5% of foot-ground contact.

The biomechanical variable of jerk was also explored as a possible measure associated with loading rate risk factors. In engineering terms, jerk is the rate of change of acceleration, which is the derivative of acceleration with respect to time. Jerk is not yet a term widely used nor researched in biomechanics but its intrinsic link to smoothness of movement in locomotion, and the link between excessive jerk and discomfort used in engineering, considering the nature of the micro spring technology being evaluated, made it worthy of investigation. To the authors knowledge few other studies into running shoes or running injuries has explored the jerk parameter. Given that loading rate is the rate of change of force, that is the derivative of force with respect to time, jerk was proposed in this work as a biomechanical parameter equivalent to loading rate, allowing the data collected from the accelerometers in outdoor trials to act as a proxy measure to data collected from force plates in the movement analysis laboratory.

As injury levels in recreational runners remain consistently high it would seem the technologies currently used in running shoes are not effectively addressing this problem. This provided the rationale for an exploration of new technology to reduce impact loading. Spring technology could offer a viable solution. Historically springs have been widely used as effective shock absorber within many industries and engineering disciplines, dampening the oscillations produced as the result of impact.

The efficacy of springs in footwear remains scientifically unproven due to a lack of published research in this area. Previous attempts to house springs in running shoes have used larger traditional coiled compression springs (examples include Spira and Gravity Defyer), compared to the micro spring technology assessed in this study. However, the question also remains as to the most effective way to introduce springs into footwear in order to achieve improved shock absorption which has been linked with reduced injury rates and has been identified as a key element of development by many running shoe manufacturers.

The spring technology explored in this thesis differs significantly from the type of compression springs used in previous running shoes. Advancements in engineering processes and methods now enable the production of small compression springs with high spring rate properties. Micro springs have been relatively available for some time but have previously only been able to be manufactured with a low spring rate, meaning very little force was required for the spring to reach full compression. The micro springs investigated in this thesis were the first in the spring making industry to be developed from a sufficient gauge of wire, and with the necessary spring geometry, to successfully complete a compression cycle under typical forces representative of those experienced when running.

Another unique property of this micro spring technology is the fact that it is pocketed. A possible barrier to using micro spring technology in running shoes to date may have been the difficulty of incorporating numerous micro springs during the manufacturing process. The micro spring technology referenced throughout this thesis is pocketed in a non-woven fabric, with each individual micro spring sealed within its own pocket by an ultrasonic weld. This allows a pad of micro springs to be fitted as a single component in the manufacturing process. Pocket springs themselves are a relatively new phenomenon used mainly within the mattress industry and are often quite large. The pocketed nature of the technology allows each micro spring to act independent to the next, rather than just having one single large spring acting alone.

This thesis reports on the use of pocketed springs within footwear for the first time, as well as examining how best to enhance a mass-spring damper arrangement within running shoes. In simple terms, a mass-spring-damper system facilitates shock absorption and takes account of the mass applying the force/impact, along with the spring and any other dampening mechanism/material in place to absorb the force/impact. The first part of this work investigates the role of pocketed micro spring technology to potentially improve running shoe shock absorption characteristics.

Whilst exploring an enhanced mass-spring-damper arrangement within sports footwear it became quickly apparent that assessing subtle but potentially important changes in the technology would be difficult in human trials due to inter and intra subject variability. A key, albeit not planned, outcome of this work was the development of a new drop rig testing machine that could replicate both rearfoot and forefoot impact loading values. Whilst other mechanical machines do exist that are capable of measuring variations in the impact properties of running shoes, most are not able to test footwear with loading rates representative of human running. In addition, most test rigs also affix the shoes directly to a metallic mechanically driven shaft to perform the testing. The drop rig testing machine developed during this research incorporated a prosthetic foot, thought to better fill and hold the running shoes more securely through the testing cycles. The drop rig proved to be a remarkably consistent tool for determining the effects of subtle differences in the design and materials used in running shoes.

Published running shoe research often chooses to focus on either biomechanics or more qualitative clinical outcome measures such as comfort and pain. This thesis acknowledges the potential importance of both and as such assesses the influence of wearing pocketed micro spring technology on pain and comfort scores, alongside a number of biomechanical measures such as loading rate, deceleration, jerk and angular velocity. The link between these different areas is considered and discussed in detail in the second half of this thesis.

1.2 Rationale and Company Involvement

The recent development of micro-spring technology, led largely for UK industry by Harrison Spinks Ltd within the mattress sector, now allows for higher density spring configurations. The ability to produce ever smaller springs allows for more to be located in a given area. Although Harrison Spinks had utilised this technological development to their commercial advantage within the bedding market, they quickly appreciated the potential of micro-spring technology within other sectors. A Knowledge Transfer Partnership (KTP), supported by Innovate UK, brought together Harrison Spinks Ltd, an innovative mattress and components business in Leeds, United Kingdom, and the biomechanics specialists of the Allied Health Research Unit at the University of Central Lancashire (UCLan) to investigate the capabilities and possible advantages of this new technology within the sports footwear sector.

KTPs serve to meet core strategic needs of UK companies and identify innovative solutions to help business growth, offering positive and meaningful outcomes for company and knowledge base alike. A fifth-generation family business, Harrison Spinks was established in

1840 and today is a leading high-end, luxury bed manufacturer and supplier of quality components to the furniture, bedding and automotive industries. Inventors of three-dimensional, fine wire micro pocket springs, Harrison Spinks are a pocket spring manufacturer specialising in the creation of unique low height pocket springs thought to offer unparalleled levels of comfort. The author of this thesis was employed as the KTP associate by the University of Central Lancashire, acting as the link between UCLan and Harrison Spinks throughout the project.

Given the versatile nature of low height pocket springs, and the thought that principles of comfort technology can be applied to a wide range of products, the idea developed to explore the role micro pocket springs could play in sports footwear. The starting point for this research project was to explore the effectiveness of high density pocketed micro springs in reducing impact forces and vertical loading rates during running, with an emphasis on achieving enhanced shock absorption in running shoes. It is important to note that although the KTP and this thesis focused on the same research project, the outcome objectives were independent and separate. Throughout this thesis Harrison Spinks provided access to micro-spring technology, not currently available within the sports footwear market, and engineering assistance and support with the aim of improving the technology to enhance the shock absorption properties of running shoes.

Throughout the project prototypes were developed by KTP project partners Intersport IC, Switzerland. The Intersport Group is the world's largest international sporting goods retailer and they took an active interest in this new technology and how it could contribute to their continuous innovation strategy. Recruiting a commercial partner was a key objective of the KTP but not of this thesis.

1.3 Thesis structure

The thesis consists of seven chapters. This introductory chapter aims to offer the rationale for choosing to explore this area of research and highlights some of the key discussion points from this work, along with gaps in this field of research. Also outlined is an overview as to the background of the research project and an explanation of external company involvement. The aims and objectives of the various studies of this thesis are highlighted.

Chapter 2 offers a review of relevant literature concerning the prevalence of running injuries in the recreational population and functional anatomy of common knee injuries. Along with detailing the biomechanical factors associated with running injuries, particular interest is paid to the role impact loading rate can play on injury risk, methodologies and conclusions of other research are explored.

Chapter 3 covers background information relevant to running shoe technology and compression spring properties. This focuses on the commercialisation of running shoes and identifies some of the claims and benefits current running shoe manufacturers suggest their footwear offers. Also included is a technical overview of compression springs and a brief history of their integration into footwear in the past.

Chapter 4 provides information regarding the equipment and basic methods used throughout the thesis. Calibration protocols, equipment specifications and sampling frequencies are detailed. Justification for the selection of the comfort and pain questionnaires used in this work is also given.

Chapter 5 and 6 comprise the main experimental components of the thesis. Chapter 5 focuses on the initial aim of exploring an enhanced mass-spring-damper arrangement within sports footwear. A flow chart can be seen at the start of chapter 5 which outlines the iterative process followed to develop a running shoe integrating pocketed micro spring technology. Five laboratory based trials with healthy recreational runners are described along with the results observed as a result of technical modifications to the technology itself. Two of the laboratory based studies utilised the new drop rig testing machine built solely to service the footwear testing needs of this project.

Chapter 6 explores changes in biomechanical parameters and knee pain/comfort scores within groups of healthy and knee pain subjects when wearing the running shoes with integrated pocketed micro springs. This includes an introduction to the study, methodology used, a detailed description of the results, a comprehensive discussion of these findings and the practical implications. This chapter introduces the concept of jerk, in addition to more widely researched biomechanical measures such as tibial accelerations and angular velocity.

Chapter 7 summarises the key points from this thesis and discusses their implications along with research limitations and recommendations for future research. Observations of the relationship between biomechanical parameters and clinical outcome measures are offered. A general review of the influence of this new technology on recreational runners and the impact of the new information gathered is also discussed. The final conclusions of the thesis are stated, relating directly back to the original aims and objectives noted at the start of this project.

1.4 Aims and objectives

There were two main aims for this body of work. Firstly, to identify whether pocketed micro spring technology could be viably and effectively integrated into a commercial branded running shoe and explore any potential changes to kinetic biomechanical parameters this technology had. In order to achieve this aim, a number of key objectives were set to;

- develop a pocketed micro spring capable of reducing impact forces experienced when running
- test and quantify the potential benefits of this technology with respect to loading rate measures in recreational runners
- establish a commercial partnership to prototype a usable final product to enable a second phase of research exploring the effect of the technology on knee injuries in recreational runners

Success in this phase would result in the existence of a running shoe with a mass-spring-damper system in the midsole.

The second aim was to explore the effect of the technology on recreational runners currently suffering with knee pain. The objectives were to;

- identify any potential biomechanical changes as a result of wearing running shoes integrating pocketed micro springs, focusing on jerk, acceleration and angular velocity measures in healthy and injured runners
- assess subject responses to clinical measures (pain and comfort) when wearing the running shoes integrating pocketed micro spring technology.

It was hoped this would allow for conclusions to be drawn as to whether reducing impact loading through the use of spring technology has any positive effect on reducing or eliminating knee pain in recreational runners and determine the significance of any potential findings.

CHAPTER 2: LITERATURE REVIEW

2.1 Search strategy

This chapter reviews the literature relevant to the biomechanical factors associated with running injuries. The search strategy was as follows. Three electronic databases were searched, along with citations in eligible articles and reviews, and the contents of recent journal issues and extended web searches, up to and including April 2018. Search terms concerning running injuries were combined with the anatomical sites, impact loading, deceleration, jerk, angular velocity, prevalence, footwear etc using and/or functions.

Numerous searches over an extended time period produced a variety of abstracts and papers. Titles and abstracts were screened and whilst no specific screening criteria was used, full text articles were targeted and selected based upon runners being recreational or competitive in order to maintain within the scope of this research. No specific exclusion criteria were put in place other than the need for the study to be written in English.

2.2 Prevalence and sites of running injuries

Despite the technological advancements and perceived improvements in running shoes, the prevalence of injuries in recreational runners is yet to show any significant sign of reduction. Running is one of the most widespread activities during which overuse injuries of the lower extremity occur (Hreljac, 2004). The incidence and prevalence of running related injuries are thought to range from between 19.4% to 79.3% (van Gent et al, 2007), and it has been previously estimated that up to 70% of runners will sustain an overuse injury during any one-year period (Powell et al, 1986).

This is further supported by a more recent study by Tenforde et al (2011), who found that overuse injuries were reported by 68% of female high school track and field athletes and 59% of male high school track and field athletes. Tenforde et al sought to evaluate "lifetime prevalence" and risk factors for overuse injuries in high school athletes currently participating in long-distance running. Twenty-eight high schools in the San Francisco Bay Area took part with a total of 442 female and 306 male athletes, aged 13-18 years, all of which were on cross-country and track and field teams. They concluded the majority of athletes currently participating in high school cross-country and track and field have a history of sustaining an overuse injury.

Various studies have provided results on the prevalence and incidence of running-related injuries using different measures of association. These include, proportion of injuries in a population (Ryan et al, 2011), number of injured runners per 100 runners (van Mechelen, 1992), number of injuries per 1000 km (Gerlach et al, 2008), and number of injured runners per 1000 hours of running (Buist et al, 2010). This makes the exact number of injuries hard to identify as inconsistent use of these measures in the literature makes comparison of injury data difficult across studies.

More recently Videbaek et al (2015) presented a systematic review of the literature for the incidence of running-related injuries in novice runners, recreational runners, ultra-marathon runners, and track and field athletes per 1000 h of running. The search conducted included PubMed, Scopus, SPORTDiscus, PEDro and Web of Science databases. 'Injuries per 1000 h of running' was selected as an important and useful measure of association that enables comparison of the risk of injury across studies. Screening of 815 abstracts left 13 original articles included in the main analysis. The year of publication for the included studies ranged from 1987 to 2014, and the studies represented populations in Australia, Denmark, Luxembourg, Sweden, the Netherlands, and the USA.

Running-related injuries per 1000 h of running ranged from a minimum of 2.5 in a study of long-distance track and field athletes to a maximum of 33.0 in a study of novice runners. Their conclusion was that novice runners face a significantly greater risk of injury per 1000 h of running than recreational runners. Limitations of this review included heterogeneity in definitions of injury, definition of type of runner, and outcome measures in the included full-text articles challenged comparison across studies. The results of this recent review suggest that injury risk is reduced the more experienced the runner, even though they may spend more time running. From the analysis, it was suggested that the majority of runners within the selected articles were categorised as 'recreational'. Therefore, this thesis focuses on the population of recreational runners as this group has the widest reaching implications and the greatest potential for improvement.

Another systematic review conducted by van Gent et al (2007) considered the incidence and determinants of lower extremity running injuries in long distance runners. An electronic search was conducted using the PubMed–Medline database. Screening criteria included studies where subjects ran >5 km per training or race, runners were recreational or competitive runners but not elite, and the study included a study population of at least 10 individuals. After examining the 1113 titles and abstracts, the final selection comprised 17 articles. Results showed the predominant site of injury was the knee. There was strong evidence that a long training distance per week in male runners and a history of previous injuries were risk factors for injuries, and that an increase in training distance per week was a predictive factor for knee injuries.

Common overuse running injuries include stress fractures, medial tibial stress syndrome, Achilles tendinitis, plantar fasciitis and patellofemoral pain. However, the most common site of injury is the knee, with patellofemoral pain being the most frequent complaint (Taunton et al, 2002). Taunton et al, investigated a total of 2002 patients with running related injuries at the AMSMC, a referral facility located on the campus of the University of British Columbia. They classified patients as having a running injury if: they had pain or symptoms during or immediately after a run, the injury was felt to be related to running, and the injury was significant enough to force them to stop running or significantly reduce their running mileage and seek medical assistance.

The high prevalence of knee pain amongst runners has been associated with highly repetitive knee joint loading, which is one of the main causes of patellofemoral pain (Rathleff et al, 2015). Net biomechanical loading on the patellofermoral joint is a major determinant of cartilage stress, and it is estimated to reach 4.5–7.6 times body weight during running (Chen et al, 2010). Hence, finding a method to reduce the magnitude of the patellofemoral joint force during running may be effective in mitigating patellofemoral pain for runners (Lenhart et al, 2014).

Neal et al (2016) conducted a systematic review and meta-analysis to investigate whether runners with patellofemoral pain have altered biomechanics which targeted interventions can modify. Neal et al further highlighted that patellofemoral pain (PFP) is recognised as the most prevalent running pathology and associated with multi-level biomechanical factors. Medline, Web of Science and CINAHL were searched from inception to April 2015 and 28 studies were included. Findings highlighted limited but coherent evidence of altered biomechanics which interventions can alter with resultant symptom change in females with PFP, particularly through a possible kinematic mechanism.

Thijs et al (2008) found that among adults, 17-21% of runners develop patellofemoral pain during a start to run program. One hundred and two novice recreational runners (89 women, 13 men), with no history of knee or lower leg complaints took part in this prospective cohort study. The subjects' standing foot posture was examined and plantar pressure measurements during running were collected. Logistic regression analysis of the 17 runners who developed PFP showed that a significantly higher vertical peak force underneath the second metatarsal and shorter time to the vertical peak force underneath the lateral heel were predictors for PFP. No significant evidence was found for an association between an excessively pronated or supinated foot posture and the development of PFP. The authors concluded that an excessive impact shock during heel strike and at the propulsion phase of running may contribute to an increased risk of developing PFP.

Hetsroni et al (2006) found that up to 43% of military recruits develop patellofemoral pain during their initial basic training. In their investigation, neither the maximum foot pronation angle nor the range of pronation was found to be significantly associated with exertional anterior knee pain, supporting the findings of Thijs et al above. However, when assessing the potential mechanisms for injury, a statistically significant association was found between over exertional anterior knee pain and pronation velocity. Angular velocity of the tibia is evaluated as part of this thesis as a possible risk factor for knee injury.

Saragiotto et al (2014) explored perceptions of risk factors associated with running injuries in a group of recreational runners. In this descriptive study, based on semi structured interviews, a total of 95 recreational runners (65 men and 30 women) between the ages of 19 and 71 years, were asked "what do you think can cause injuries in runners?". The average running experience of the subjects was 5.5 years and approximately 45% had experienced a running-related injury in the past. Recreational runners mainly attributed injury to factors related to training and running shoes. Runners expressed great concern about their running footwear, as the following direct quote from subject highlights clearly: "…I think if you do not have good shoes appropriate for your foot type, you will get injured, since you are wearing the wrong shoes…". Lack of cushioning, heel height, and excessive wear or usage time of the shoes were all mentioned in this study as possible risk factors. This suggests that most runners are acutely aware of the potential role running shoes can play in injury prevention and the perceived importance they place upon equipment.

2.3 Functional anatomy of knee injuries associated with running

There appears to be no clear consensus in the literature concerning the terminology, aetiology and treatment for pain in the anterior part of the knee (Thomee et al. 1999). Frequently patellofemoral pain syndrome (PFPS) is used as an all encompassing term for patients experiencing a variety of symptoms from the patellofemoral joint with different levels of physical impairment and pain. For example, some runners diagnosed with PFPS will experience pain sufficient to prevent them from training, whilst others may still be able to run as per their normal routine despite suffering from some degree of pain.

The patellofemoral joint consists of the patella, the distal and anterior parts of the femur, articular surfaces and surrounding supporting structures. Dynamic stabilisers of the patella include the pes anserinus and semimembranosus muscles, rotating the tibia inward, the biceps femoris muscle, rotating the tibia outward, the vastus medialis muscle, pulling the patella medially, the vastus lateralis muscle, pulling laterally, and the vastus intermedius and rectus femoris muscles, pulling proximally/laterally. At full knee extension, the patella rests on the suprapatellar bursa. During knee flexion from full knee extension, the distal part of the patella comes in contact with the lateral femoral condyle at 10 to 20° of knee flexion, and the patella then follows an S-shaped curve through the trochlea (Thomee et al, 1999). Patellofemoral compression forces increase with increasing knee angles up to 90° of knee flexion and can reach up to 8 times bodyweight (Grayson, 1990).

Three major contributing factors thought to increase the risk of developing PFPS are malalignment of the lower extremity, muscular imbalance and overactivity. However, where clinical studies have not been able to demonstrate alignment differences and muscular balance differences between patients with PFPS and healthy individuals, several studies have discussed overloading and overactivity as the stimulus for developing and exhibiting PFPS. In a study aimed to comparatively examine the effects of minimalist, maximalist, and conventional footwear on the loads experienced by the patellofemoral joint during running, Sinclair et al (2016) found that peak patellofemoral force and pressure were significantly larger in conventional (4.70 ± 0.91 BW, 13.34 ± 2.43 MPa) and maximalist (4.74 ± 0.88 BW, 13.59 ± 2.63 MPa) compared with minimalist footwear (3.87 ± 1.00 BW, 11.59 ± 2.63 MPa). In this study, twenty male participants ran over a force platform at 4 m/s, lower limb kinematics were collected using an 8-camera motion capture system allowing patellofemoral kinetics to be quantified using a musculoskeletal modelling approach and differences in patellofemoral kinetic parameters were examined using one-way repeated measures ANOVA. They concluded that as excessive loading of the patellofemoral joint has been associated with the aetiology of patellofemoral pain symptoms, the investigation indicated that adapting footwear may be able reduce runners' susceptibility to patellofemoral disorders.

2.4 Biomechanics factors associated with running injuries

2.4.1 Ground reaction forces

In 1980, Cavanagh and Lafortune reported that during distance running maximum vertical ground reaction forces of more than two times an individual's body weight are typical. In their study, ground reaction forces and centre of pressure patterns were studied in 17 subjects running at 4.5 ms^{-1}. The subjects were classified as rearfoot or midfoot strikers according to the location of the centre of pressure at the time of first contact between foot and ground. The mean peak to peak force components were 3 BW, 1 BW and 0.3 BW in the vertical, anteroposterior and mediolateral directions respectively. Body weight (BW) in this case refers to the weight of the subject tested in a trial and is a typical reporting measure when discussing the magnitude of force parameters. These ground reaction forces at heel strike suggests runners may be at risk of joint problems.

Approximately 75% of endurance runners demonstrate a heel strike pattern (Hasegawa et al. 2007). They filmed four hundred and fifteen runners during a half marathon and found the percentage of rearfoot strikers increases with the decreasing of the running speed, and conversely the percentage of mid foot strikers increases as the running speed increases. It is thought that runners who habitually heel strike have significantly higher rates of repetitive stress injury (Daoud et al 2012), therefore much emphasis is placed upon achieving optimum shock absorption in the heel region of specially designed running shoes. Of the 52 runners observed by Daoud et al, 36 (69%) primarily used a rearfoot strike and 16 (31%) primarily used a forefoot strike. Approximately 74% of runners experienced a moderate or severe injury each year, with those who habitually rearfoot strike having approximately twice the rate of repetitive stress injuries than individuals who habitually forefoot strike.

Ground reaction force measurements are often used to describe the external loading conditions in running (Grimston et al, 1991), however internal joint loading may be different from external loading. Direct measurements of internal loads can be difficult to perform and so modelling is often the chosen method. Most modelling methods use the magnitude of muscle force and intersegment moments, along with weighting factors to predict internal joint loads experienced during various activities. Inverse dynamics models have been used to estimate loading of the knee and ankle joints at impact (Scott and Winter 1990), yet it is argued that such studies failed to consider the temporal nature of the loading. Previous research has focused heavily on the magnitude of loading forces but more recent findings discuss the importance of the time component of loading as well. The rate of loading and specifically initial loading rates are the primary focus and outcome measure of chapter 5 of this thesis, in an attempt to quantify the importance of the temporal aspect of loading when running.

2.4.2 Impact loading rate

The impact experienced at the termination of the swing phase of gait initiates a transient shock through the body that has the potential to cause injury (Shorten, 2000). Whittle (1991) concluded that impact shock is dependent on two key factors, the quantity of the change in momentum and the duration over which the change in momentum occurs. This highlights the importance of both the magnitude of the force and the time component when reporting the nature of impacts. The magnitude of the shock is linked to the incidence of overuse injuries and can be lessened by increasing the duration over which the foot is decelerated (Garcia et al, 1994).

Impact loading of the lower extremity is thought to contribute to injury because it generates high stresses and strains in skeletal tissues, which as a result generate high levels of elastic hysteresis than can contribute to injury over repeated cycles (Daoud et al, 2012). Higher rates and magnitudes of impact loading have been shown to correlate significantly among rearfoot strike runners with knee pain (Davis et al, 2010).

In support of the hypothesis that initial impact phase is an important time frame of running stance in relation to selected injuries also comes from non-running studies. Radin et al (1991) observed 37% higher loading rates of vertical ground reaction force at heel strike during walking in subjects with activity related knee pain when compared to a control group. The results detail statistically significant differences between the two groups within a few milliseconds of heel strike. In the knee pain group, the heel hit the floor with a greater impact in this brief interval. Just before heel strike, there was a faster downward velocity of the ankle with a larger angular velocity of the shank. The follow through of the leg immediately after heel strike was more rapid with larger peak axial and angular accelerations of the leg echoed by a more rapid rise of the ground reaction force. The higher loading rate just after heel strike was present in enough knee pain subjects and absent in enough normal subjects to create a statistically significant difference between the two groups.

Among the experimentally measurable mechanical features of impact during the running step, Samozino et al. (2008) showed that time to impact force peak and loading rate were the most discriminant parameters and the most directly related to the magnitude of the foot–ground impact shock as quantified with skin-mounted accelerometers. Loading rate, identified as the average time derivative of vertical ground reaction force between the beginning of foot–ground impact and the time to impact force peak, is therefore thought to influence the risk of impact injuries. This gives an average loading rate between two points but does not consider the instantaneous loading rate within this period. Wide acknowledgement of loading rate as an important consideration when assessing running injury risk has led to further exploration of potentially influential time components within this variable.

This assumption is further supported by a recent systematic review by Zapdoor and Nikooyan (2011). After an initial search resulted in a total number of 503 articles and abstracts, 13 studies were selected as eligible for inclusion in the meta-analysis. They reported that vertical ground reaction force for the first peak and the second peak was similar between the control group and the group suffering from stress fractures, whereas loading rate differed between the two groups. Results showed no significant differences between the ground reaction force of the lower-limb stress fracture and control groups ($P \geq 0.05$). However, significant differences were observed for the average and instantaneous vertical loading rates ($P \leq 0.05$). Definitions for average (AVLR) and instantaneous (IVLR) vertical loading rates differ from study to study. In the studies included in this systematic review, the AVLR was defined as the change in the GRF divided by the time-period, while the IVLR was considered as the maximum of the VLRs calculated at different time samples in the whole time-period.

Crowell and Davis (2011) defined instantaneous vertical loading rate (IVLR) as the maximum slope of the vertical ground reaction force curve between successive data points in the region from 20% of the vertical impact peak to 80% of the vertical impact peak, see figure 2-1. They defined the average vertical loading rate (AVLR) as the slope of the line through the 20% point and the 80% point. They explored gait retraining to reduce lower extremity loading in runners. Ten runners (six females and four males) with peak positive tibial acceleration greater than 8 g, measured in an initial screening, participated in the retraining program. During the retraining sessions, subjects ran on a treadmill and received real-time visual feedback from an accelerometer attached to the anteromedial aspect of their distal tibias. Tibial acceleration and vertical ground reaction force data were collected from subjects during over ground data collection sessions held pre-training, post-training, and at a 1-month follow-up. Peak positive acceleration of the tibia (48%), vertical force impact peak (19%), and average (32%) and instantaneous (34%) vertical force loading rates were all reduced immediately following the gait retraining. These reductions were maintained at the 1-month follow-up. It was suggested that this may reduce their risk of stress fractures. As with most studies exploring loading rates during running however, only loading in the vertical direction was considered, with anterior/posterior nor medio/lateral loading rate data not being presented. Chapter 6 of this thesis aims to investigate in detail the multi directional components of loading rate.

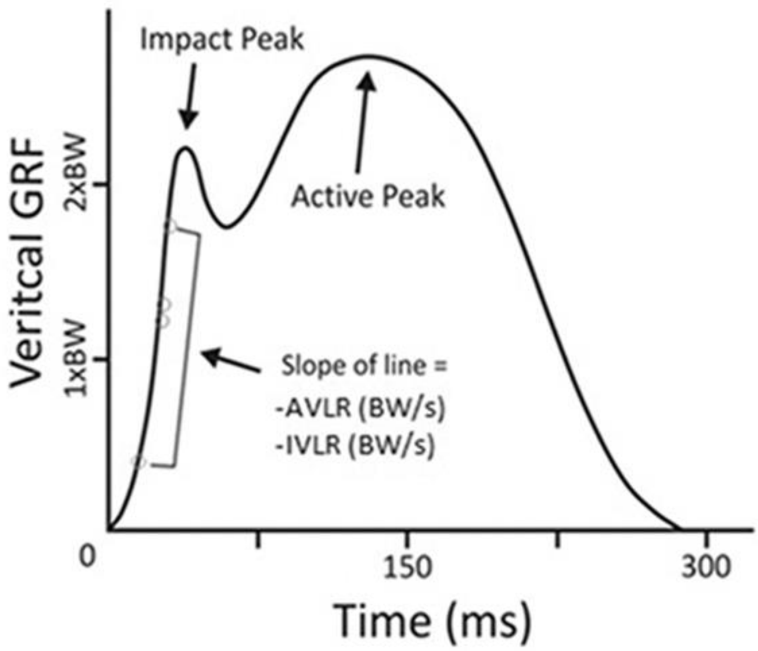

Figure 2-1: Typical GRF curve showing AVLR and IVLR

Other measures of impact shock have included vertical tibial deceleration. A rearfoot strike pattern will in most instances result in a very distinct vertical impact peak, the magnitude of which has been positively correlated to tibial shock. Davis et al (2010) assessed vertical loading rate values, along with tibial accelerometery and ground reaction force data, of a group of female rearfoot strike runners who had reported injuries over a two-year period. These values were compared to those of a group who had never experienced a running related injury. 240 female runners, aged 18-40 years took part in the study, each ran a minimum of 20 miles per week. Subjects ran over ground at 3.5 m/s, a typical speed for a recreational runner. Only injuries diagnosed by a medical professional were included. Iliotibial band syndrome, anterior knee pain and tibial stress fracture were the top three injuries sustained.

The vertical impact peak, vertical average loading rate (VALR), vertical instantaneous loading rate (VILR) and peak tibial shock were extracted from 5 trials and averaged for each subject. The vertical average loading rate for the uninjured group was 62.4 BW/s, while for the injured group it was 72.1 BW/s. Independent t-tests were used to statistically assess the data. A significant difference was identified between the two groups for three out of the four variables measured, peak tibial shock ($p=0.018$), vertical impact peak ($p=0.041$) and vertical average loading rate ($p=0.028$).

Davies et al (2010) concluded that an increase in impact loading rate amplifies the risk of developing a running related injury. The fact this study included all running injuries rather than looking at one specific injury increases the significance of these results as it suggests that loading rate is a key risk factor in the development of a number of different running injuries rather than just one in particular. Interestingly, the peak vertical force values were identical between groups, further supporting that it is the rate of loading that is important in the development of running injuries and the magnitude of vertical ground reaction force is not a sensitive predictor.

Milner et al (2006) found significantly greater instantaneous and average vertical loading rates and tibial shock in runners who had suffered from tibial stress fractures. In this study, female runners with a rearfoot strike pattern, aged between 18 and 45 years and running at least 32 km/week were recruited. Kinematic and kinetic data was collected during overground running at 3.7 m/s using a six-camera motion capture system, force platform, and accelerometer for 20 subjects with a history of tibial stress fracture and 20 age and mileage-matched control subjects with no previous lower extremity injuries. The mean vertical instantaneous loading rate for the retrospective tibial stress fracture group and control group was 92.56 BW/s and 79.65 BW/s respectively (p=0.036) with an effect size of 0.59. The mean vertical average loading rate for the retrospective tibial stress fracture group and control group was 78.97 BW/s and 66.31 BW/s respectively (p=0.041) with an effect size of 0.56.

Tis is supported by Pohl et al (2002) who reported a significantly greater maximum instantaneous load rate albeit in a plantar fasciitis group compared to a control group. Twenty-five female runners with a history of plantar fasciitis were recruited and a group of 25 age and mileage matched runners with no history of plantar fasciitis served as a control group. Subjects ran over ground while kinematic and kinetic data were recorded using a motion capture system and force plate. A substantially greater instantaneous vertical loading rate was found in the plantar fasciitis group (100.5 BW/s) compared to the control group (82.9 BW/s) (p=0.037, effect size=0.34). Pohl et al concluded that a history of plantar fasciitis in runners may be associated with greater vertical ground reaction force loading rates. A limitation is that the cross-sectional nature of this study makes it difficult to determine whether the differences in variables between the injured and control groups were the result of the injury or were present before injury. Any treatment that runners may have sought for the injury could have altered their biomechanical measurements.

Davies et al (2010) only reported on vertical loading and did not report on whether anterior/posterior and medial/lateral loading rates are also having a contributing effect. They found peak tibial shock values were also significantly higher for the injured group compared to the uninjured group, 5.9g and 4.8g respectively (p=0.018). However, again only the vertical deceleration component was considered, anterior/posterior and medial/lateral decelerations were not explored. Although smaller in magnitude, anterior–posterior ground reaction forces applied to the lower extremity during the loading phase of stance may also influence loading of the tibia. In the Milner et al (2006) study, loading rates during braking also increased in runners with a history of stress fracture. The mean braking instantaneous loading rate for the retrospective tibial stress fracture group and control group was 20.35 BW/s and 19.29 BW/s respectively. The mean braking average loading rate for the retrospective tibial stress fracture group and control group was 8.54 BW/s and 8.37 BW/s respectively. However, in both variables no significant differences were noted. Milgrom et al (1989) support the importance of assessing anterior-posterior loading, in their study it is suggested that the most significant biomechanical factor associated with tibial stress fracture in humans has been the bending strength of the tibia about the anterior/posterior axis of bending, with movements occurring in the medio/lateral direction.

Vertical impact peaks and loading rates have been demonstrated to be strongly correlated to peak tibial accelerations (Lafortune, 1995). Despite the study focusing on a single volunteer subject, it was one of the first to publish the importance of measuring all three components of acceleration to quantify the magnitude of the shock experienced by the lower limbs during locomotor activities. Tibia acceleration measures have also revealed high correlations between peak acceleration and ground reaction force parameters (Hennig and Lafortune, 1991). Using data from six male subjects, Henning and Lafortune compared ground reaction force and tibial acceleration parameters for running. A bone-mounted triaxial accelerometer and a force platform were employed for data collection. A high negative correlation was found for the comparison of the peak axial acceleration with the time to peak vertical force. They concluded, the peak tibial acceleration could be well estimated using vertical force loading rate and peak horizontal ground reaction force as predictors.

In addition, Greenhalgh et al (2012) observed impact peak, average loading rate and instantaneous loading rate of vertical ground reaction force were significantly correlated with peak tibial accelerations. In this study thirteen participants ran at 4.0m/s over a force platform whilst simultaneous tibial accelerations and GRF information were recorded. The ground reaction force variables analysed identified that the strongest correlation (r=0.469) exists between the peak initial vertical loading rate and the peak tibial acceleration. From the above it can be summarised that ground reaction force measures are adequate for the prediction of bone accelerations and vice versa.

2.4.3 Jerk

With the literature pointing to the significant role impact loading plays in the aetiology of overuse running injuries, the question as to how this can be tested in an ecologically valid environment is raised. As described in the section previous, almost all clinical studies into impact loading rate and running to date have been conducted in a laboratory based setting using force platforms. In order to ensure conclusions founded upon laboratory trials are correct, it would seem prudent to conduct similar trials in an outdoor environment and on a surface more typically representative of that which a runner would usually run, for example the pavement. For this to be achievable a measurement equivalent to impact loading that negates the need for a force platform is required.

In engineering terms, jerk is the rate of change of acceleration, which is the derivative of acceleration with respect to time, and as such the second derivative of velocity, or third derivative of position. Jerk is a vector, the standard SI units of which are m/s^3. Given that loading rate is the rate of change of force, that is the derivative of force with respect to time, jerk can be proposed as a biomechanical parameter equivalent to loading rate. Although jerk is not yet a term widely used in biomechanics, some researchers have begun explore the concept. It is important to note that impact forces can be measured on the ground, on the shoe and on the lower extremity.

Eager at el (2016) describe jerk as "the change in force, an increasing or decreasing force on the body". They describe various areas of physics and engineering where jerk can be observed and suggest that jerk should always be considered when vibration occurs and smoothness of movement is deemed to be of importance. A key concern highlighted is that the human tolerance to acceleration has been measured and is well understood whereas the human tolerance to jerk is yet to be explored in any great detail.

Park et al (2006) conducted a study to evaluate the differences in normalised jerk according to shoes, slope and velocity during walking. Eleven test subjects used three different types of shoes (including running shoes) at various walking speeds and gradients on a treadmill. It was hypothesised that there would be differences in jerk evident across all three assessed variables. It was also assumed that running shoes would have the lowest values for normalised jerk because all subjects were most accustomed to wearing these shoes. Results demonstrated significant differences in jerk measurements, in all three planes of motion, between the three different shoes types, suggesting that footwear can influence levels of jerk.

Tack et al (2006) also described how the smoothness of different movements have been carried out by using jerk in engineering fields of study. In their study they used normalised jerk, calculated in anterior-posterior, medio-lateral, vertical and overall direction to explore walking speed. The purpose of this work was to evaluate differences in gait pattern using jerk as a representation of smoothness of movement whilst changing walking speeds. This methodology was used to propose a subject's preferred walking speed based on the smoothness of the movement pattern and jerk profile.

Other researchers, such as Hreljac and Fukaya, have referenced jerk as an assessment measure of stride smoothness in runners and other athletes. Hreljac (2000) used a jerk-cost function parameter to quantify movement smoothness at heel strike contact in runners and non-runners. This study demonstrated that competitive runners tend to exhibit smoother strides than recreational runners during both running and fast walking. However, to the author's knowledge, no other published research has used this technique in the exploration of footwear and injury properties.

2.4.4 Angular velocity

Despite impact factors largely dominating the literature associated to running injury aetiology, other variables have been seen to influence injury risk. The majority of studies in the biomechanics literature that investigated lower extremity actions have reported on the kinematics of individual lower extremity joints rather than addressing the interaction between the joints (Hamill et al, 1999). Fewer studies, however, have investigated the coupling of the subtalar joint and the knee joint during running.

A number of studies have sought to present relationships between impact peak, pronation, and forces at the subtalar joint during contact phase in rearfoot running. Stacoff et al (1988) produced calculations to show that the material properties of a shoe midsole (altered from Shore A20 to A50) largely influence the rearfoot movements during initial contact (increase in pronation velocity from 7 to 25 rad/s). In comparison, the impact peak (1550 to 1600 N) and the ankle joint forces (2500 to 2700 N) changed very little. They concluded, running shoe design should be focused not purely on shock attenuation, but equally on control of rearfoot movement at initial contact.

Nigg et al (2003) suggested increased internal tibia rotation could increase a runner's risk of injury. They assumed that knee pain in running can result from the transfer of foot eversion to internal rotation of the tibia. Internal rotation of the tibia is coupled with ankle eversion during stance. Compensatory femoral internal rotation due to large tibial internal rotation in late stance may lead to injurious knee joint stresses (Tiberio, 1987). Internal rotation properties of the tibia are typically quantified in more recent studies via the gyroscope capabilities of an accelerometer attached to the skin frequently on the anterior-medial aspect of the tibia.

Grewel et al (2014) used body worn sensors incorporating a tri-axial accelerometer, gyroscope and magnetometer to compare and quantify changes in tibia internal-external rotation range between shod and barefoot running. Results suggested that habitual shod runners transiting to barefoot running can have negative impact from significant increase in range of internal-external rotation of the tibia. Using body worn sensors allowed exploration of three dimensional changes in knee joint kinematics during stance phase under different running conditions in an out of laboratory environment.

Wearable motion sensors have been considered as an inexpensive alternative to optical motion analysis systems for obtaining kinematic data. The optical motion analysis system has been acknowledged to provide precise human kinematic data, and the data from wearable motion sensors have been proven to be highly correlated with it (Liu, Inoue, & Shibata, 2009). Acceleration of human body segments and joint angular velocity can be measured by the digital sensors including accelerometers and gyro sensors.

Although the magnitude of tibial rotation during running has been reported relatively widely within the literature, fewer researchers have explored angular velocity of the tibia, particularly in relation to the transverse plane. Shih et al (2014) used a 3-axis gyroscope sensor to observe the kinematic changes of the foot during intense running, finding a significantly high correlation between ankle ROM and peak angular velocity in the frontal plane. However, tibia angular velocity in the transverse plane was not reported.

A systematic review by Norris et al (2013) into method analysis of accelerometers and gyroscopes in running gait found that of the 38 articles included in the review only 2 looked at angular velocity whilst running. Most focused on tibial acceleration and shock attenuation. The two studies that explored angular velocity were as follows. Bergamini et al. (2012) utilised an IMU consisting of a tri-axial accelerometer and a tri-axial gyroscope placed on the lower back to provide analysis of amateur and elite sprinters. Channells et al. (2005) placed an acceleration measurement unit consisting of 2 bi-axial accelerometers on the athlete’s shin, they then performed a series of walking, jogging and running trials. Angular velocity data was then generated through integration which was compared to angular velocity derived through the same calculation using motion capture.

Transverse plane angular velocity of the tibia during running has been associated with injury mechanisms which will be explored in chapter 6 of this thesis. Investigating this area further may lead to a greater understanding of stability during impact loading and its potential role as a risk factor for running related knee injuries.

2.5 Running shoe cushioning systems

The literature strongly supports the assertion that vertical force parameters can impact upon risk and aetiology of injuries in runners, however the question regarding the extent to which footwear cushioning can influence vertical force parameters still remains. Clarke et al (1983) explored the effect of different footwear. Two shoes were tested, one firm and one soft, to determine the effects of varied amounts of cushioning on eight vertical force parameters. The soft shoe had 50% more cushioning as measured by an instrumented impact tester. Ten male subjects, (mean weight = 68.0 kg) ran at a speed of 4.5 m/s (6 min/mile pace) and contacted a Kistler force platform. Five right footfalls were collected for each shoe on each subject. They found that certain vertical force parameters, including impact loading rate, vary depending on footwear worn. It was found that the time taken to reach the vertical force impact peak was significantly longer in the soft shoe (hard = 22.5 ms, soft = 26.6 ms).

Aguinaldo and Mahar (2003) conducted a similar study to evaluate the effect of running shoes, with two types of cushioning column systems, on impact force patterns during running. A 4-column multicellular urethane elastomer midsole, 4-column thermoplastic polyester elastomer midsole, and 1-unit EVA foam midsole were tested. Kinematic and ground reaction force data were collected from 10 normal participants. Three floor-mounted force platforms were used to sample ground reaction force data at 1,000 Hz. Significant differences in impact force ($p=0.02$) and loading rate ($p=0.005$) were seen between the two cushioning column systems. The average loading rate for the 4-column thermoplastic polyester elastomer midsole was 45.6 ± 11.6 BW/s compared to 57.9 ± 12.1 BW/s for the 4-column multicellular urethane elastomer midsole. In this case, average loading rate was calculated from the linear slope between footstrike and the time onset of peak vertical GRF, in other words peak force divided by time to peak force. This study showed that even in similar shoe types, impact force and loading rate values could vary significantly with midsole cushioning constructions. Any alterations in impact force patterns induced by lower limb alignment and running speed were thought to be negligible, as participants did not differ in ankle position, knee position or speed during trials.

Ruder et al (2015) explored the effect of highly cushioned shoes on tibial acceleration in runners. 7 healthy male runners, typically running at least 10 miles per week in standard running shoes were recruited. Prior to data collection, tri-axial accelerometers were strapped around participant's ankles bilaterally. Variables of interest were the peak tibial accelerations in the vertical, medial, lateral and posterior directions, as well as the vertical average loading rates. Results suggested that running in highly cushioned running shoes results in increased tibial shock compared with a standard neutral shoe. Data also suggested there may be a moderate relationship between vertical acceleration and vertical average loading rate variables. This was stated as being extremely useful in the clinic when a force plate is not available or when monitoring of vertical loading during running in the community is desired.

2.6 Gaps in current literature and original contribution to knowledge

Despite a significant amount of research, the optimum running shoe for injury prevention and reduction of pain when running remains elusive. Below are some of the gaps in current literature around running injuries and the original contribution to knowledge this thesis aimed to address:

- exploring specifically the initial 5% of the loading rate profile to assess the potential influence of new running shoe technologies to reduce values compared to current market leading running shoes and its relationship to pain reduction
- the role angular velocity of the tibia, in all three planes of motion, plays in running related knee injuries, observing the potential effect of introducing newly developed technology into running shoes when compared to regular running shoes
- introducing a proposal for an equivalent measure for loading rate, jerk, able to be recorded in outdoor running trials through IMU sensors rather than laboratory based trials using force plates
- evaluating all three directional components of acceleration, angular velocity and jerk to determine relative contributions of anterior-posterior and medial-lateral aspects in comparison to vertical aspects
- assessment of the potential of pocketed micro spring technology to influence pain and comfort measures in healthy recreational runners and those suffering from suffering from knee pain

CHAPTER 3: BACKGROUND

3.1 Popularity of recreational running

Once viewed as a sporting activity practiced only by competitive athletes and school children, today running has become an extremely popular pastime pursued by millions of recreational participants worldwide. Thought to stem from the creation of marathon events open to the public in America, the running boom of the 1960's and 1970's, paved the way for road running to be viewed as both inclusive and attractive. Nowadays, running sees a healthy increase in participation year on year.

According to Sports Marketing Surveys Inc, international participation research into running has revealed that the UK's running population has reached 10.5 million (SMS INC, 2014). They conclude that one in five adults run four or more times a year, while 25% of under-18s also qualify as active runners under these criteria. It is also thought that the average rate of running participation in the UK is 72 times per year, or 1 to 2 times per week, and that 55% of runners do at least a third of their running out on the roads, whilst a quarter do at least a third still outdoors, but off-road. While shorter distances remain more popular, longer distance running is also gaining participants in the UK. 800,000 runners, or 10% of the UK adult running population, competed in a marathon, half-marathon or triathlon in the last 12 months. The current total of European runners exceeds 80 million; approximately 36% of 15 to 65-year-old European population (Asociación RUVID, 2012). According to the National Sporting Goods Association, running continues to show strong and consistent growth annually as total running participation (ran at least 6+ days per year) was up nearly 4% overall in the last year (Running USA, 2013). Recent Sports and Fitness Industry Association US running participation numbers indicate a 2.9% increase in the number of participants that run 50+ days per year, increasing the total amount to 29,478,000 in the US in 2012 (Running USA, 2013).

Running in the UK has benefitted significantly from the London 2012 Olympic Games. The exploits of Mo Farah and co, along with the high-profile drive for a lasting Olympic legacy, have led to a statistically significant increase in running participation figures (Sport England, 2012). Running is currently the UK's second most popular sport according to Sport England's Active People Survey (2014-15). With 80% of runners choosing 'road/pavement' as the surface they usually run on when questioned as part of Sport England's SQSE 4 survey (2012).

This continued increase in recreational running popularity is mirrored by marathon and half marathon participation figures. Since the inaugural race in 1981, the number of people taking part in the London marathon has risen from 7700 to 38,000 in 2015 and is now capped, over 250,000 people apply to take part (Virgin London Marathon, 2015). Similarly, an analysis of participation in ultra-marathons in North America showed that both the number of competitors and competitions significantly increased over the last decade (Hoffman et al 2010).

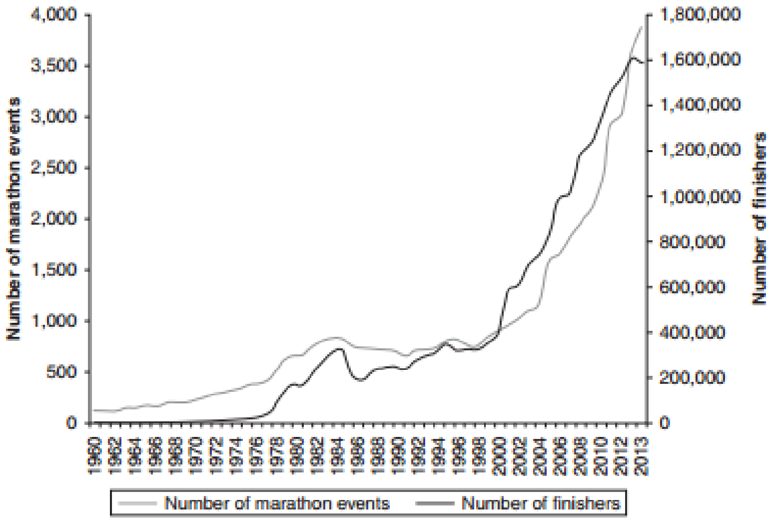

Figure 3-1: Evolution of the number of marathon events and marathon finishers worldwide, 1960-2013. (Taken from J. Scheerder et al. 2015)

For many running represents a low cost, simple and social method of improving fitness and wellbeing. An increasing number of runners are interested in and actively seek out further information on the various aspects associated with recreational running, including footwear, apparel, local races etc. Runner's World is currently the most popular running magazine, published in twenty-two countries with a five million global readership (Runner's World October 2013). With more than one million Twitter followers Runner's World is an influential medium when considering training plans and equipment. Each quarter Runner's

World publishes a shoe guide designed to inform runners which shoes are best performing based on their own internal laboratory tests and wearer trials.

3.2 Commercialisation of running shoes

The popularity of running along with the continued emphasis on injury prevention and performance improvement has led to a rapid increase in the sports technology market. It is thought that more than 350 million pairs of running shoes are sold each year in the USA alone (Running USA, 2013). In 2010, close to £2 billion was spent on sports footwear in the UK, with estimates of a 7% volume increase by 2015 (Euromonitor International, 2011). Recent reports suggest that US running shoe sales totalled a record high in 2012, up 23% on the previous year. Sales also grew an additional 16% in 2013 (Running USA, 2013).

The average price of a pair of running shoes in the UK is now close to £100, with some running shoes new to the market reaching £180 per pair. According to Running USA's 2013 National Runner Survey of 30,000 core runners, 68% reported spending $90 plus on a pair of running shoes in the past 12 months, and purchasing an average of 3 pairs of shoes in the last year. In September 2012 Runner’s World published a shoe lab report on the climbing prices of running shoes. In the two years prior to the report, the price paid per ounce of running shoe had risen by 24%. The average price per pair of running shoes in 2004 was $95 in the USA, by 2012 the figure had risen to $115.

Running is often viewed as a cheap sport however, in 2013 Runner’s World calculated the average recreational runner will spend over $22,000 on shoes and clothing over a lifetime. An increasing proportion of the sports footwear market is becoming dominated by running shoes, largely led by the ever increasing recreational following for the sport. This is perhaps most apparent through the level of marketing and advertising global sport brands now spend on running. Where previously football was the only sport where brands would choose a celebrity sports star to promote their products, running is now subject to a similar investment. Puma recently renewed an endorsement contract with Usain Bolt, reported to be worth an estimated $10 million a year (Reuters, 2013). Other brands also have a team of celebrity athletes endorsing their footwear, for example Nike have a sponsorship deal with Olympic champion Mo Farah and his training partner Galen Rupp.

With sports shoe technology now a multi-billion pound industry some consumers are beginning to question whether the price they are paying for product is down to celebrity branding and marketing claims rather than the underlying product value.

3.3 Brand marketing and evidence based claims

Almost every new running shoe released to market by the major sports brands makes reference to a new technology or modification that they claim will enhance performance or reduce the risk of injury. Few brands publish supporting evidence to substantiate these claims and choose to focus on promotion of the product rather than the science behind the innovation. Although evidence based marketing is an emerging concept in a number of other sectors, it has not been widely adopted in the sports shoe market. Possible reasons for this include the importance brands place on ensuring their individual product development process is kept secret from other brands in a highly competitive market, and a potential hesitancy to deviate from a marketing strategy that has been very successful to date.

One such example that has captured the attention of the media recently is Adidas's successful reinvigoration of its running shoe range. The Adidas Boost melts together 1000s of special energy capsules into a midsole that they claim provides more energy return than any other foam cushioning material in the running industry. However, they fail to provide published evidence to support this claim. Adidas have invested heavily in marketing materials targeted at convincing the consumer that this shoe can return more energy to the runner but nowhere within its print or online platforms is there reference to a scientific study or comparative data against other running shoes. Recent data published within the independent academic community has also begun to question the clinical efficacy of this footwear. In a study aimed at examining the 3-D kinetics and kinematics when running in Adidas Boost trainers, Sinclair et al (2014) found that tibial accelerations, peak eversion, and tibial internal rotation, were significantly greater in the footwear designed to improve energy return. On the basis of these observations, they suggested that the Adidas Boost may place runners at an increased risk from chronic injury.

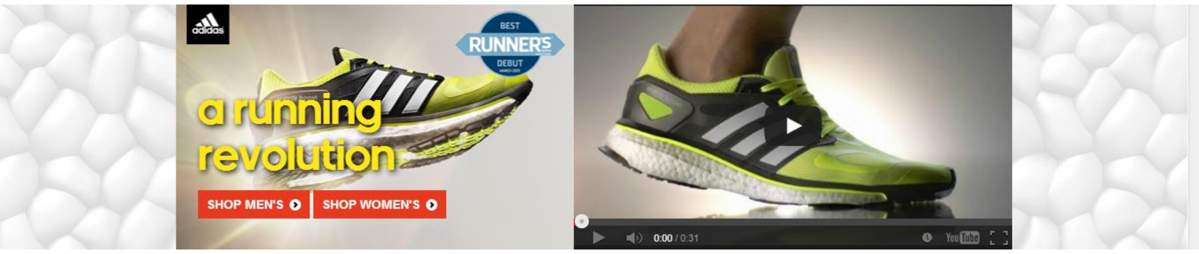

Figure 3-2: Promotional material for the Adidas Boost running shoe, 2013. (Taken from http://www.adidas.co.uk/running, 2013)

Adidas is not the only brand not forthcoming when it comes to releasing publicly available evidence to support their marketing claims. A number of the most popular and well established running shoes on the market are also reluctant to adopt an evidence based marketing strategy. Further examples include the Nike Pegasus which claims to absorb more impact for softer landings and smoother transitions. Arguably the go to shoe for many road runners, the Asics Kayano, claims to provide a more efficient gait and more medial stability to compensate for over pronation. Brooks suggests the DNA cushioning material used in their Glycerin model disperses impact and provides ideal comfort and protection.

Almost every brand selling shoes in the running market is making similar claims. As so many of the leading brands choose to base their claims on, and name their technology after, scientific and in most instances biomechanical parameters, the question remains why do so few choose to release supporting data. As many of the areas the brands choose to focus on (impact, stability, pronation etc) have been widely published within research literature with well-defined test protocols this poses an interesting question.

There is a strong argument to suggest that evidence based marketing and evidence based purchasing would benefit both the retailers and consumers in the running shoe market. Scientific or empirical evidence could allow brands to offer a more compelling reasoning as to why runners should select their shoes. This evidence may in turn allow runners to better select footwear most appropriate to their needs, thus improving customer satisfaction with the product. Many brands talk about utilising human testing and scientific trials during their development processes, so it is fair to assume that testing does take place but results are frequently kept a closely guarded secret.

Newton Running is a brand that, within their marketing materials, places a heavy emphasis on helping people find the right position to run in, promoting a forefoot strike to allow runners to strengthen their natural running motion. Much like its competitors, Newton's running shoes make claims that their technological components, such as the biomechanical sensor plate, allows runners to stride more efficiently and with more stability. However, unlike other brands, Newton Running is one of very few brands that detail independent testing and results on their website.

On the Newton Running website it states testing comparing Newton shoes to other running shoes was conducted by an independent and certified mechanical test laboratory, Knight Mechanical Testing (KMT). KMT specializes in military, aerospace and medical testing, and has no ties to the running shoe industry. The KMT test protocols, contracted by Newton, repeatedly and continuously impact the shoes with forces simulating the speed and cadence of a runner. Comparative ground impact force and rate of loading data is provided, ranking the various types of shoes tested in order of test performance.

The mechanical nature of such tests allow for high levels of repeatability and precision whilst providing interesting comparisons between component materials with respect to impact and durability. However, Newton have chosen not to explore these finding further by performing human trials to see if such data would correlate to findings collected from a human test sample and are yet to publish any data. Currently, Newton is providing a comparison between different running shoes but not investigating the effect that the differences between the shoes have on the runners themselves. As so many of their claims centre around the runner, efficient gait, more stability etc., it seems insufficient to deduct these associations and causality from mechanical data without any human based data. Whilst mechanical testing offers a certain insight into footwear performance, on its own it limits how much one can accurately deduce in terms of the effect of impact forces on joint loading and rotation properties.

The patent process is essential to any brand wanting to protect a new technological development or design. Patent documentation includes detailed information about the invention, typically a justification for the invention, along with evidence to suggest that the invention is novel. However, much like with marketing materials, in many cases there is little evidence to support the claimed benefits of the new technology. The majority of running shoe technology patents provide published data to justify why the new technology is needed, and the problem it is attempting to address. For example, Nike Inc.'s patent for athletic shoe with rearfoot strike zone (1995) focuses on how the benefits realised in cushioning have been offset by a degradation of shoe stability, offering a number of references to support this statement. Nike Inc. suggest that a sole with a segmented rearfoot strike zone "attenuates force applications and shock associated with heel strike, without degrading footwear stability during subsequent phases of the running cycle" however, this is not supported in the publicly available patent documentation by any scientific evidence. As not all literature is open access, it may be that further evidence is held within private documentation.

The majority of major sports footwear brands now target runners with a certain foot strike pattern when marketing their running shoes. Research by Richards et al (2009) explored whether the current practice of prescribing distance running shoes featuring pronation control systems and elevated cushioned heels tailored to an individual's foot strike was evidence based. Literature searches of a number of databases found no original research that met the study criteria either directly or via systematic reviews, suggesting the prescription of this shoe type to distance runners is not evidence based.

With so many running shoe brands to choose from, each claiming to utilise revolutionary technology and companies frequently releasing new and improved models, it has become very difficult for consumers to differentiate between shoes and make an informed decision on purchase with little or no evidence of shoe performance. Researchers have begun to investigate and compare different running shoe technologies. Kong et al (2009) looked at the effect of shoe degradation on running biomechanics, comparing maximum vertical force and loading rate in new and worn shoes, along with a number of kinematic variables. Three types of footwear using different cushioning technologies (air/gel/spring) were compared by 24 runners (14 men and 10 women). After a longitudinal study, consisting of a 200 mile road running intervention, no between group difference among the three footwear types were found in any measured variables. Kinetic and kinematic variables remained unaffected by different cushioning technologies, suggesting no significant differences in the performance of popular running shoes.

This suggestion is further supported by Clinghan et al (2008) who investigated if more expensive running shoes have better cushioning and comfort than low cost alternatives from the same brand. Three pairs of running shoes were purchased from three different manufacturers at three different price ranges: low (£40–45), medium (£60–65) and high (£70–75). 43 male subjects participated in the main study. The study concluded that low and medium cost running shoes in each of the brands, provided the same, if not better, cushioning as high cost running shoes. The study assessed cushioning performance through plantar pressure rather than ground reaction force.

In 2012 a joint investigation by the BMJ and BBC Panorama found “a striking lack of evidence” to support claims about improved performance and recovery for many sports products, including trainers. The investigation, broadcast on Panorama “The Truth About Sports Products”, aimed to explore the science behind the marketing hype of a multibillion-dollar industry. A research team from the Oxford Centre for Evidence Based Medicine were unable to find any good quality evidence to support that trainers specially designed by the major brands reduce injury. They concluded that it is “virtually impossible for the public to make informed choices about the benefits and harms of advertised sports products” (BMJ, 2012).

There is no evidence to suggest that current athletic footwear differ significantly in impact absorption in relation to manufacturer, model, or cost, when tested blindly using force platform or accelerometer technology during normal running (Nigg 1986). Robbins and Waked (1997) go one step further and state “pre-existing beliefs of protection against injury formed through deceptive advertising of athletic footwear attenuates user caution thereby amplifying impact”.

3.4 Running shoe technology evolution

Each new running shoe released to market boasts of new and improved technological advancements aimed at enhancing the individuals running experience. Previously, running shoes had been very simplistic in design, largely consisting of a foam based midsole (often Ethylene-vinyl acetate (EVA) or Polyurethane (PU)) attached to a traditional fabric upper. However, over the past few years, due to breakthroughs in material science and an ever-increasing focus on research and development, running shoe manufacturers have begun to introduce a number of different materials into the construction of running shoes. Gel and dual density foam constructs are just two examples of the popular midsole components introduced in an attempt to enhance the shock absorbing qualities of running shoes.

Another popular and growing trend in the running community is the emergence of minimalist and barefoot running. In an attempt to return back to basics, some manufacturers have moved towards developing footwear with very little, and in some cases no underfoot cushioning (Nike Free, Vibram Five Fingers etc.). It is suggested by some researchers that barefoot running conditions will force a forefoot landing pattern with less force and greater efficiency than a heel striking landing pattern. While regular running shoes afford greater comfort and cushioning, it is claimed they do little to mitigate the impact of a landing, and thus reduce resultant injury rates (Lieberman et al., 2010). They report that forefoot striking barefoot runners have lower loading rates compared to shod rearfoot striking runners due to more plantarflexion and ankle compliance. In contrast, Altman and Davis (2012) observed step frequency and loading rate in barefoot condition was not significantly different from loading rate in midfoot striking shod conditions. Yet, step frequency was higher, for both conditions compared to rearfoot strikers.

A number of other studies have opposed these findings. Willy and Davis (2013) found that running in a minimalist shoe increased loading of the lower extremity over standard shoe running, bringing into question the benefits of minimalist footwear. Moore et al.'s study (2015) supports this suggestion. They concluded that whilst a seven-week minimal shod transition programme was shown to decrease several kinetic variables, it was evident that both barefoot and minimal shod conditions led to greater loading rates and peak pressures than shod running. Williams et al (2012) suggested the increase in power absorption at the distal segments observed during barefoot running may result in an increased risk of injury at the foot and ankle. In a review of relevant literature, Jenkins and Cauthon (2011) conclude that there is not currently any definitive evidence that either confirms or refutes improved performance and reduced injuries in barefoot runners. Conclusions about impact intensity in different footwear conditions are still debated, largely due to a disparity in the experimental methods used (type of shoes used, familiarisation of subjects with barefoot running, distance and duration of trials).

To predict the longevity of current trends such as minimalist and barefoot running is a futile exercise in a world dictated by branding and fashion. In 2013 Runner's World predicted a major shift back to heavily cushioned running shoes, suggesting Brooks Transcend and Hoka One to be the big sellers in spring 2014, they were correct. Increasingly popular "maximalist" shoes, with their deep, heavily cushioned soles, are viewed as running's new wonder products. Leo Manzano, an Olympic medallist in the 1500 meters, runs in the most popular maximalist shoe brand, Hoka One One ®, which has double the cushioning of standard running shoes. In 2014 Hoka sold more than 550,000 pairs, which cost $130 to $170 each, and its $48 million in sales were up 350 percent from 2013 (New York Times, 2015).

Perhaps a more useful approach is to analyse how individual brands have developed and improved their premium models over time. The Asics Kayano has enjoyed a popular following amongst recreational runners since its release in 1993. The first model utilised the technology of the day and was one of the first Asics shoes to have gel in the heel and forefoot. By the 6th model in 2000, the Kayano included Asics' new Impact Guidance System to assist with stability, and an upper made from synthetic leather rather than suede. In 2006, the Kayano 12 introduced Solyte, a super light foam leading to a weight reduction. In the years since, Asics have incorporated memory foam, guidance lines, mesh fabrics, and further weight reductions in subsequent models and the Asics Kayano 23 was released in late 2016. The justification for alterations in design and materials through various models of the Kayano have never been quantified with respect to shoe performance, this is also the case with many other popular running shoes.

3.5 Compression spring properties

A spring is an object with elastic properties used to store mechanical energy. There are a variety of different spring types, the design of which take advantage of different energy storage management, they include extension springs, torsion springs, constant force springs etc. however, most springs are classified as compression springs. A compression spring is designed to operate with a compression load, so the spring gets shorter as the load is applied to it.

Springs can be made from a number of different materials including hard drawn carbon steel, stainless steel, tempered silicon chromium, bronze, titanium and more recently plastic. In order to prepare carbon steel for spring manufacture it must first be drawn into rounded wire form. This is achieved through a wire drawing process from steel wire rod. Dependant on the application, standard and speciality rods are bought. Steel rod is frequently accompanied by a chemical composition analysis. Dependent upon the content of carbon, the pressure on the wire results in deformation or absorption. Wire is drawn on modern multi-die machinery that forces the rod through high pressure dies with rapid rotational force, gradually reducing diameter as it travels through each die. There are a number of factors that can influence the physical properties of the final hard drawn wire, these include amongst others machine speed, cooling mechanisms and coating options. British Standard specifications exist to ensure quality of drawn wire for springs of different applications, such as BS 4637:1970 carbon steel wire for coiled springs. These standards outline tolerance and testing requirements such as tensile strength and torsion measurements.

Considerations when making a compression spring are physical dimensions, load, rate, and travel requirements. Most compression springs are manufactured on some form of CNC (Computer Numeric Control) machine. CNC machining is a process used in the manufacturing sector that involves the use of computers to control machine tools through precisely programmed commands. Feed rolls feed the wire from the first wire guide to the second wire guide, this tool is selected according to wire diameter. There is one wire guide before the rolls and another after. The second wire guide feeds the wire towards the arbor to begin shaping the coils. The arbor is the half moon shaped pin which the wire goes under and around once it has hit the coiling points. The coiling points are two pins which shape and form the coils by interfering with the spring wire's straight path and slightly making a continuous bend. The pitch tool slides up and down to also interfere with the now coiled wire and pushes the coil out to make pitch. Finally, the cutter comes down once the spring is formed and cuts the wire where the last coil ends therefore completing the process.

Spring rate tests are often run to check dimensions are in line and that the rate and working loads can be met. British Standard 1726-1 provides guidance on methods of specifying and tolerancing coiled compression springs. It outlines the most common spring rate measurement where springs are tested at 20% and 80% of the safe deflection from the nominal free length of the spring, and then the spring rate recorded as a N/mm value.

Springs are almost invariably the highest stressed component in a manufactured item, and so are potentially the most susceptible to failure. Fortunately, most springs are safely designed and therefore seldom fail. Nonetheless, an appreciation of the mechanisms by which springs could fail is important to understand. Statistics compiled by the Institute of Spring Technology on failure investigations carried out in their laboratory over a twelve-year period show that fatigue is by far the most important mechanism by which springs may fail. The fatigue mechanism may be brought about by corrosion or wear, highlighting the necessity to perform durability and situational tests prior to application and make necessary modifications to mitigate against potential failure.

As long as they are not compressed beyond their elastic limit, most springs obey Hooke's Law, which states that the force with which the spring pushes back is linearly proportional to the distance from its equilibrium length, see equation 3-1.

$$F = -kx$$

Equation 3-1: Hooke's Law, where x is the displacement vector (distance and direction the spring is deformed from its equilibrium length), F is the resulting force vector (magnitude and direction of the restoring force the spring exerts), and k is the rate, spring constant or force constant of the spring, (depends on the spring's material and construction). The negative sign indicates that the force the spring exerts is in the opposite direction to its displacement.

If made with constant pitch, conical springs will have a variable rate. However, a conical spring can be manufactured to have a constant rate by creating the spring with a variable pitch. A larger pitch in the larger-diameter coils and a smaller pitch in the smaller-diameter coils will force the spring to collapse or extend all the coils at the same rate when deformed. For the purpose of impact resistance and cushioning or support it could be beneficial to have a variable spring rate, the implication of this would be the potential of the spring to offer greater resistance the greater the force applied.

3.6 Springs in footwear

Energy return is a current buzz phrase used within the running community. A spring could be considered a dynamic symbol and an object capable of both absorbing and releasing energy. It has been suggested that elastic energy storage and recovery within the cushioning system of a running shoe is a desirable quality that can enhance performance. However, it has been suggested that when the energetics of a running shoe cushioning system is compared to other passive energy exchange systems in the runner, the potential benefits of energy return are limited (Shorten 1993). It was further predicted that the energy dissipated by wellconstructed running shoes is small and unlikely to have any direct effect on the energetics of the runner's body as a whole.

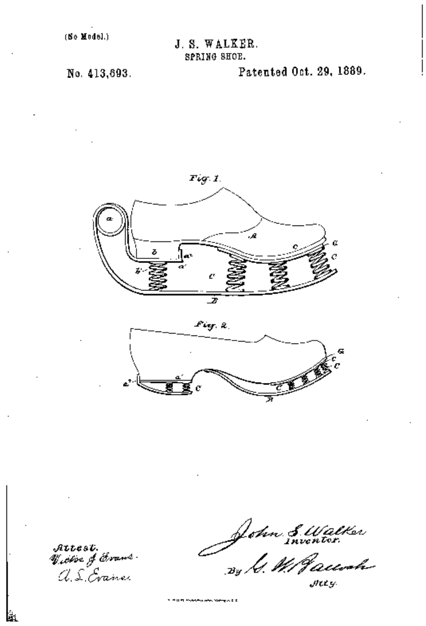

Figure 3-3: Illustration from Patent US413693A spring shoe granted October 1889

Springs embedded within footwear is not a new idea. In 1889, John S Walker was granted a US patent on a spring shoe, see figure 3-3 above. There have since been many other spring patents focused specifically on athletic shoes with the aim of absorbing shock and reducing the number of sports related injuries. These patents, like many other sports shoe midsole technology patents, do not quantify the claimed benefits of the invention publicly. In 1995, Alvaro Gallegos was granted a patent for a spring athletic shoe which it was claimed provided superior shock absorbance and energy return, however no evidence was published to substantiate this claim in the public domain.

Spira was one of the first companies to bring sprung footwear to the consciousness of runners. Spira claimed their WaveSpring® technology improves cushioning and impact protection. To date Spira have sold close to one million pairs of shoes and have a number of footwear models for various activities (Spira, 2013). Through its online platform, the company talks in detail about testing of both its components and complete running shoe. However, very little detail is given with respect to methodology and minimal explanation given to support claims. For example, Spira’s largest selling point is based on the suggestion that their shoes can reduce peak impact forces by up to 20% and return approximately 96% energy however, no information is provided as to what tests were run to produce these figures and no supporting data has been published.

Figure 3-4: Spira WaveSpring® (USA)

Following on from Spira’s introduction into the running market, a number of other sprung footwear brands began to emerge, such as Gravity Defyer and Z-Coil, with a focus on pain relief and protection. Both purport to absorb shock but neither provides details of any testing, nor do they quote published data to support these claims.

Figure 3-5: Gravity Defyer (USA) and Z-Coil (USA)

The most recent brand to invest in the spring and energy story is Adidas with the 2013 launch of Springblade running shoes. With a key emphasis on energy return, the Springblade integrates 16 high-tech polymer blades onto the outsole of the shoe. As with Adidas's other running shoes, striking claims are made about performance. Adidas state that a "band of power in the heel absorbs energy when loaded and unleashes it for maximum launch" (Adidas, 2013). There seems to be no published data to further explain or support such statements.

The efficacy of springs in footwear remains scientifically unproven due to a lack of published research in this area. The question also remains as to what would be the most effective way to introduce springs into footwear in order to achieve the improved shock absorption goal chased so widely by the running shoe manufacturers.

CHAPTER 4: METHODS

4.1 Ethical approval

All studies were approved by the STEMH (Science, Technology, Engineering, Medicine and Health) ethics committee at the University of Central Lancashire (see appendix A). Prior to data collection written informed consent (see appendix B) was gained from all subjects.

4.2 3-D kinematic motion capture

Although the studies outlined in this thesis are focused primarily upon kinetic rather kinematic biomechanical outcome measures, 3-D kinematic motion capture was still utilised and served to support the kinetic data collection. Firstly, the foot kinematic data collected in the human based trials outlined in Chapter 5, played a vital role in the development of the drop rig methodology of later studies. It was used to establish the appropriate drop mass and drop height required to replicate vertical peak forces and vertical impact loading rates experienced during human running trials. Further details are outlined in section 4.4. Secondly, during the initiation of drop rig trials in an attempt to enhance the mass-spring-damper system within the iterative prototypes, the Movement Analysis Laboratory was configured as such that kinetic force plate data collection was controlled only through the Qualisys Track Manager software to enable a faster sampling rate.

4.2.1 Camera system

The Qualisys motion capture system (Qualisys Medical AB, Gothenburg) was used for 3-D motion data collection in the Movement Analysis Laboratory at the University of Central Lancashire. The system uses high quality digital cameras which emit short infrared pulses that are reflected back to the camera by retro reflective markers. The retro reflective markers are often placed on the full body or certain section of a participant. The marker positioning used in this study is explained further in chapter 4.2.4. The cameras used were Qualisys Oqus 310 series models.

Figure 4-1: Qualisys Oqus 310 camera

4.2.2 Calibration

Qualisys Track Manager (QTM) is the software used to record 2-D data from the Qualisys cameras. In order to resolve this 2-D data into 3-D data information about the position and orientation of each camera is required. Calibration is needed to ensure the accuracy of this data. Prior to each data collection session, a static and dynamic calibration procedure was conducted to define the global coordinate system.

For the static calibration procedure, an L shaped reference structure (Calibration Kit, Qualisys Medical AB, Gothenburg) was placed in the data measurement area. The structure provides positional information with respect to a known frame of reference (Richards 2008). The L shaped reference structure is an aluminium frame with 4 retro-reflective markers, one at each proximity, one in the right-angled corner, and one 90mm from the right angle up the longer length of the frame.

For the dynamic calibration procedure, a T shaped calibration wand (Calibration Kit, Qualisys Medical AB, Gothenburg) with two retro-reflective markers was moved through the anticipated movement volume in all three planes for 30 seconds with a default sampling frequency of 100 Hz. Information recorded with respect to camera positioning and orientation is used by the calibration algorithm with Qualisys Track Manager.

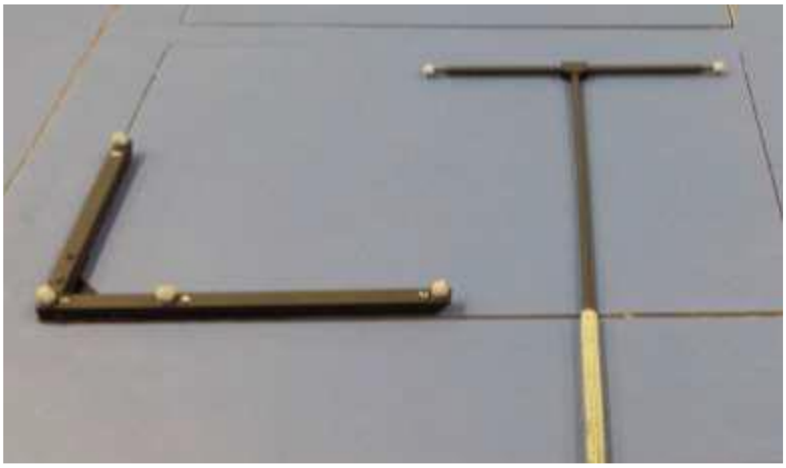

Figure 4-2: Calibration Kit, Qualisys Medical, L shaped reference structure and T shaped calibration wand

Calibration is used to identify the error associated with the camera system. This is assessed through average residual values of the retro-reflective markers picked up by each camera. Average residual values give errors (in mm) from the distance between the 2-D marker ray and its corresponding 3-D point. Previous publications have indicated that a value below 1mm for each camera can be deemed acceptable in line with the manufacturer's guidelines. For each calibration procedure carried out prior to each data collection session in the Movement Analysis Laboratory average residual values did not exceed 1mm.

4.2.3 Camera placement

The Qualisys motion capture system (Qualisys Medical AB, Gothenburg) was configured as per the figure below. The figure demonstrates a representation of the camera positioning and the data measurement area. Ten cameras were placed on tripods and elevated to a height of 2 metres. The cameras were spaced approximately 1.5 metres apart with spacing left between cameras 1 and 10 and, cameras 5 and 6 to allow participants a pathway through which to run.

Figure 4-3: Qualisys camera positioning at the Movement Analysis Laboratory at UCLan

4.2.4 Marker positions

When conducting the laboratory based running trials of the various studies outlined in chapter 5 to explore an enhanced mass-spring-damper configuration of the running shoes, retro-reflective markers were placed on anatomical landmarks and the running shoes to provide a frame of reference. The markers used were 10mm spheres, covered in reflective tape, attached to a small circular black foam rubber plinth. Double sided hypo-allergenic tape was used for adhesion of the markers to the skin or shoe.

In order to achieve segment modelling, retro-reflective markers were attached to the lower limb and feet of each subject by the author. The shank was modelled from markers over the medial and lateral epicondyles of the femur to define the proximal end and over the medial and lateral malleoli to define the distal end. The thigh was defined using the hip joint centre as the proximal end and the medial and lateral epicondyles of the femur as the distal end.

Throughout chapter 5 the tracking and modelling of specific segments was achieved using the Calibrated Anatomical System Technique (CAST) first proposed by Cappozzo et al (1995).

CAST offers the ability to model each body segment in six degrees of freedom. The method involves identifying an anatomical frame for each segment using anatomical landmarks and segment marker clusters. The technical frame marker clusters were placed in relatively central and lateral positions on both the shank and the thigh. The clusters consisted of four non-collinear markers attached to a curved black plastic plate. Manal et al (2002) established clusters of four markers mounted to a lightweight shell is the most effective method for segmental tracking. The corners of the plates were marked using ink to check for movement of the plates during the trials. It is the anatomical markers that provide an anatomical co-ordinate system for each segment by defining proximal and distal ends. The segment co-ordinate system is then referenced through acquiring a standing static calibration of the model relating the technical frame marker clusters to the anatomical co-ordinate system axes. The anatomical landmark markers were removed prior to running trials after the standing static calibration was completed.

Historical gait analysis nearly always considered the foot as a single segment system. More recently it has become acknowledged that the foot and ankle joint is better described in terms of rearfoot, midfoot and forefoot. Previously restrictions with regards to the capability of biomechanical measurements to identify numerous small markers meant that is was only possible to model the foot as a single segment. However, it is now possible, through multiple cameras, correct camera positioning and careful marker placement to track the foot as separate segments through multiple gait cycles in six degrees of freedom (Richards 2008).

Scott and Winter (1991) were some of the first to recognise that both the ankle joint and subtalar joint are capable of providing movement in all three planes simultaneously and that any motion in any plane would be due to combined motion at both joints, thus reflecting that a single degree of freedom at the foot would be an over simplification. Leardini, et al. (1999) concluded it was necessary that during dynamic evaluation the shank and foot should be detailed as a “multi-joint mechanism” and proposed this may establish the origin of many foot and lower limb injuries.

In more recent times, a number of researchers have developed foot models where the rearfoot, midfoot and forefoot are modelled as separate segments, these include Carson et al (2001) and MacWilliams et al (2003). Many of the recent studies exploring the effect of footwear variants on running biomechanics have used some form of multi segment foot model (Morio et al. 2009, Shultz et al. 2012). Whilst most authors now agree on the need of a multi segment model to successfully model the foot, there is still little consensus on the best model.

The issue of placing markers onto footwear is currently an area of debate. There are questions as to whether this method provides the same data as on the foot itself. It is well recognised that there is a potential for a foot to move within a shoe (Milani and Hennig, 2000). However, putting markers on the shoe is currently the only practical way we can look at and assess the effect of shoe modification or different footwear types on running performance. It may be possible to modify shoes to allow markers to be placed onto the foot but the involves alterations to the structure of the footwear, which is often an integral contributing factor to the results in itself.

The model used in laboratory running trials in this project was a three-segment foot model, with markers placed on the shoe and not the foot itself. This model allows analysis in six degrees of freedom between three segments of the foot. The rearfoot is defined with four markers, with two markers positioned offset to one another on the rear of the shoe, and a further two markers on a line projected down from the medial and lateral malleoli. The midfoot is also defined with four markers. To minimise the number of markers required on the shoe, the two markers projected down from the medial and lateral malleoli define the proximal segment end, and markers on the lateral aspect of the 5^{th} metatarsal and medial aspect of the 1^{st} metatarsal define the distal end. An additional tracking marker is added on the dorsal surface between the proximal and distal anatomical landmarks. The forefoot is defined by the proximal markers on the lateral aspect of the 5^{th} metatarsal and medial aspect of the 1^{st} metatarsal, and the distal markers on the medial and lateral distal part of the shoe.

The 3-segment foot model was used in the classification of rearfoot and forefoot strikers in the laboratory based running trials outlined in Chapter 5. Although all participants were asked to self-identify as rearfoot strikers, the kinematic data collection offered a visual aid to ensure robust classification. When reviewing and assessing the lab based running trials, if the GRF at initial ground contact passed posterior to the ankle joint, the participant was confirmed as a rearfoot striker. If the GRF at initial ground contact appeared anterior to the ankle joint, or beneath the metatarsal heads, the participant was classified as a midfoot or forefoot striker and as such excluded from these studies.

An example of the full marker set can be seen on the example subject below.

Figure 4-4: Complete marker set on a subject

4.3 Kinetic data collection

4.3.1 Force platforms

Force platforms measure and record the ground reaction forces, and their point of application. They are considered as a basic but fundamentally important tool for gait analysis (Richards 2008). A ground reaction force is made up of three components, vertical forces, anterior-posterior forces and medio-lateral forces. Strain gauge force platforms produce 6 channels of analogue data output, forces in the x, y and z, and moments in the x, y and z. These are calculated from readings taken at four pylons situated in the corners of the force platform. A single analogue channel representing a single force is then multiplied by a scaling factor to convert this voltage into force in newtons. A huge number of publications exist on the application of strain gauge platforms in clinical research and sport.

The force platforms used throughout this project are the AMTI BP400600 (Advanced Mechanical Technology Inc., Boston). The force platform dimensions are 600mm length by 400mm width. They are strain gauge platforms and utilise the principle of strain, a ratio of changes between original dimensions and the deformed dimensions. All force platform data was collected through Qualisys Track Manager software allowing synchronisation to 3-D kinematic information.

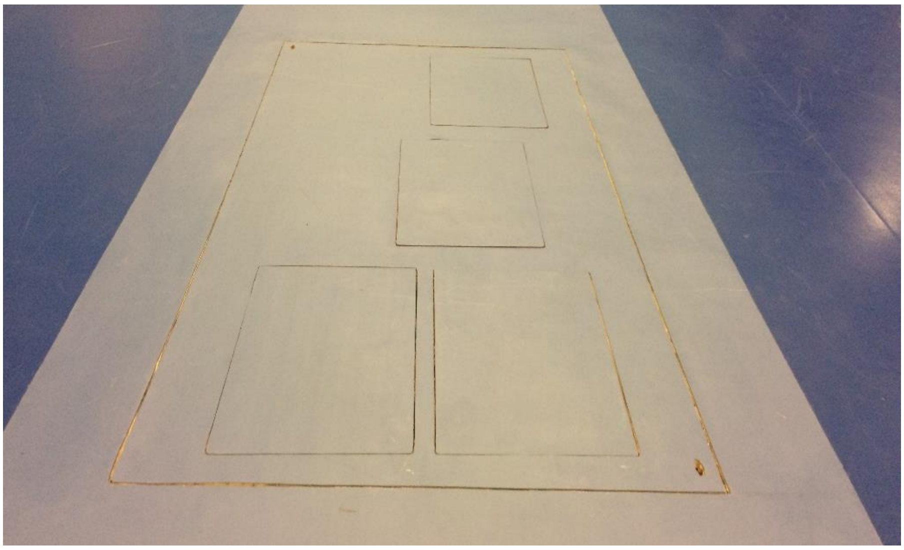

Figure 4-5: AMTI BP400600 force platforms

4.3.2 Accelerometer

Accelerometers are either uni axial or tri axial. A uni axial accelerometer measures the acceleration component in one direction only whilst tri axial accelerometers measure acceleration components in three directions. When the accelerometer is mounted to the distal tibia during running the objective is usually to quantify bone accelerations. Although it has been concluded that attaching the accelerometer directly to the tibia using invasive bone techniques such as Hoffman pins will provide a more reliable representation of acceleration time history (Nigg and Herzog, 2005) it has become common place to use skin mounted techniques due to increased practicality. Johnson and Simkin (1993) found that by securely appending a lightweight yet rigid mounting device to the skin and then attaching the accelerometer, tibial impact accelerations can be accurately quantified. Like force platforms, accelerometers can either be strain gauge or piezoelectric.

The justification for using accelerometers to explore impact forces and loading rates is outlined in chapter 3.4. The Delsys Trigno Lab Wireless IM System (Delsys Inc., Boston, MA) was used to investigate tibial accelerations and tibial angular velocity of runners with and without knee pain, running in both their regular running shoes and the commercial running shoes containing pocketed micro spring technology (see chapter 6). Each wearable sensor has a built in triaxial accelerometer and a transmission range of 40 metres. The sensor has dimensions of 37mm length x 26mm width x 15mm depth.

Figure 4-6: The Delsys Trigno Lab Wireless IM system and the Delsys Trigno accelerometer sensor

During the testing accelerometers were affixed to the anterior aspect of the distal tibia. The top of each sensor is shaped with an arrow to aid in the determination of orientation. In each instance the arrow was placed parallel to the tibia. The sensors are attached to the skin using a hypo-allergenic interface, manufactured from medical grade adhesive approved for dermatological applications. Using the interface promotes a high quality electrical connection between the sensor bars and the skin, minimising motion artifacts. A single accelerometer was placed on both the right and left tibia for testing. Measurements of distance from the anterior projection of both the medial and lateral malleolus to the sensor were taken to try best ensure sensor placement remained the same for returning participants.

When in use the system streams data to EMGworks Acquisition and can be recorded for later analysis in EMGworks Analysis. For this application, the Delsys Trigno Lab system was supported on a 32-bit Windows 7 laptop.

4.3.3 Calibration

Calibration of the embedded force platforms was achieved by placing small retro-reflective markers in each corner of each force platform. A two second data collection period using QTM provided positional information which allowed the software to resolve the position and location of each force platform.

Figure 4-7: Force platforms calibration set up with retro-reflective markers

The Delsys Trigno Lab Wireless System (Delsys Inc., Boston, MA) stores calibration information for sensors which have been paired with it. When collecting data with EMGworks, this calibration information is used to accurately display measured values. After a pairing operation is completed, the system automatically searches for pre-existing factory calibration data on the particular sensor. Factory calibration data are a string of numbers and letters which encode the calibration values for a specific sensor. Factory calibrations are specific to a single sensor and will not be accepted by the software for use on another sensor. At any time a nominal, “default” calibration may be selected for a sensor, or the specific factory calibration may be re-entered.

4.4 The drop rig

Assessing the impact of relatively small changes in shoe design can be challenging when testing relies on human participants. Intra and inter subject variability during the lab based human running trials outlined in chapter 5 presented a clear example of this. Throughout the iterative process of developing a commercially viable running shoe integrating the pocketed micro springs, whereby a number of prototypes were produced, each providing a physical change from the previous prototype as a result of the findings of prior testing, the need for a standardised method of impact assessment became apparent.

Between-stride variability during locomotion can play both beneficial and detrimental roles depending on the parameter under investigation (Miller et al 2008). Lees and Bouracier (1994) tested the hypothesis of ‘movement stereotype’ measuring four ground reaction force variables, two reflected the shock absorption characteristics of a runner plus footwear, including the magnitude of the vertical force impact peak. Thirteen out of the fourteen subjects showed substantial differences in one or more variable, with only one subject showing no difference in all variables across the different test sessions. It was concluded that this has implications for the testing of sports equipment and especially when determining efficacy of different designs of equipment.

This challenge led the author to consider the relative pros and cons of bench testing vs human testing. Testing any product against specifications in a simulated environment rather than with human participants will always have its limitations with regards to ecological validity. Yet, as the challenge to evaluate small incremental changes made to each prototype iteration using human participants increased, in order to assess the repeatability of the running shoes’ response to impact, it was decided a standardised method of assessment was required.

Previous authors have investigated durability performance and dampening parameters of running shoe midsoles using mechanical devices. Bruckner et al (2010) used a 'Hydraulic Impact Test' and the Runner's World team use a similar instrument. There is even an ASTM standard, ASTM F1976 – 13 (Standard Test Method for Impact Attenuation of Athletic Shoe Cushioning Systems and Materials) used to test running shoes. This test method is used by athletic footwear manufacturers and others, both as a tool for development of athletic shoe cushioning systems and as a test of the general cushioning characteristics of athletic footwear products, materials and components. It was suggested that adherence to the requirements and recommendations of this test method provides repeatable results that can be compared among laboratories. This test method uses an 8.5 kg mass dropped from a height of 30-70 mm to generate force-time profiles that are comparable to those observed during heel and forefoot impacts during walking, running and jump landings.

However, the instruments noted above all share one key limiting factor. All involve a metal mass impactor which does not represent the structure and properties of the human foot. In particular this offers no flexibility and does not include any representation of the skin and soft tissues on the plantar surface of the foot. In order to address this problem, a new drop rig testing machine was developed by the author with assistance from a team of Harrison Spinks engineers that could replicate both rearfoot and forefoot impact loading during running. The drop rig consisted of a variable height and mass, and incorporated a multiflex prosthetic foot (Blatchfords, UK), which could be adjusted to simulate forefoot, rearfoot or flatfoot impacts.

The multiflex prosthetic foot used as part of the drop rig allowed for flexibility at the ankle and within the carbon fibre keel and incorporated a leaf spring to enable heel strike flexion capabilities not demonstrated in a regular metal mass impactor. The prosthetic foot also offered the added benefit of filling the entire running shoe cavity rather than just the heel region as a metal impactor typically would, with a plastic cosmesis, which at least in part represents the skin and soft tissues on the plantar surface of the foot. This not only enabled the shoes to be fitted more securely to the prosthetic foot, but also allowed a closer representation to the human foot than a metal impactor. This also facilitated the testing of forefoot impacts using the drop rig, which utilised the flexion of the carbon fibre keel of the prosthetic foot allowing some bending of the running shoes during impact.

The ability of the drop rig to be adjusted to simulate forefoot, rearfoot or flatfoot impacts was achieved by the capability to manipulate the angle of ground contact. The prosthetic foot attached to the weighted mass via a steel pylon. The angle of this pylon in relation to the force platform below was manually adjustable using a simple fixing device operated by locking nuts and an allen key.

In order to verify and decide upon the shoe-ground contact angles for rearfoot and forefoot impacts the literature was again reviewed. It is reported that the distribution of angles at initial foot contact range from -10° for forefoot first contacts to 35° for extreme rearfoot contacts, as established from high speed video analysis measurements of the foot contact angles of Boston Marathon participants (Shorten and Pisciotta, 2017). A recent laboratory-based study by Paquette, Milner and Melcher (2016), found the average foot contact angle for 5 consecutive foot strikes for habitual rearfoot runners to be between 11.4° and 11.8° dependent upon the time point at which it was recorded. Forty-four recreational runners between 18–45 years of age participated in this study, and initial foot contact angle was established from kinematic data using an 8-camera three-dimensional motion capture system. For the drop rig studies outlined in chapter 5 of this thesis, 11.5° was used as the initial angle of contact for rearfoot impacts and -5° was used as the initial angle of contact for forefoot impacts.

Various weights and drop heights were explored to determine if the vertical peak forces and vertical impact loading rates experienced during human running trials could be replicated through the drop rig. In order to achieve this, data from the laboratory based human testing of the first and second prototype was revisited to establish the typical vertical peak force and vertical average loading rate from the trials run in the popular branded running shoes. As all of the subjects from the previous two laboratory-based studies had been heel strike runners, the rearfoot impact was used to verify the drop rig forces.

As a starting point an initial mass of 70kg and a drop height of 30mm was tested but this resulted in peak forces in excess of 3500N and loading rates in excess of 140 BW/s. After experimenting with a variety of weights and drop heights it was found that with a mass of 40kg and a drop height of 10mm, a peak force of 2000N and a loading rate of 80 bodyweights/second could be achieved with a standard running shoe. This also provided a realistic representation of the drop height of the human foot in terminal swing phase just prior to ground contact as well as providing normal physiologic forces and loading rates experienced in human running testing.

Although the creation and utilisation of this new drop rig design was essential to the research with regards to the development of an enhanced spring mass damper system integrating pocketed micro spring technology, the author does recognise the limitations of using such a device. The prosthetic foot used as part of the drop rig, although it provides a better representation than a solid foot, does not fully represent the human foot. The prosthetic foot was also attached to the pylon through a rigid fixed mechanism. Both of these factors no doubt represent a significant over simplification of the dampening mechanism evident in a human foot and lower limb.

During the prototype testing process the drop rig was successfully used to evaluate the loading properties of two popular market leading running shoes and the pocketed micro spring technology prototypes. Further details of the drop rig methodology, with respect to number of repetitions, operational specifics etc. can be found in chapter 5.6.

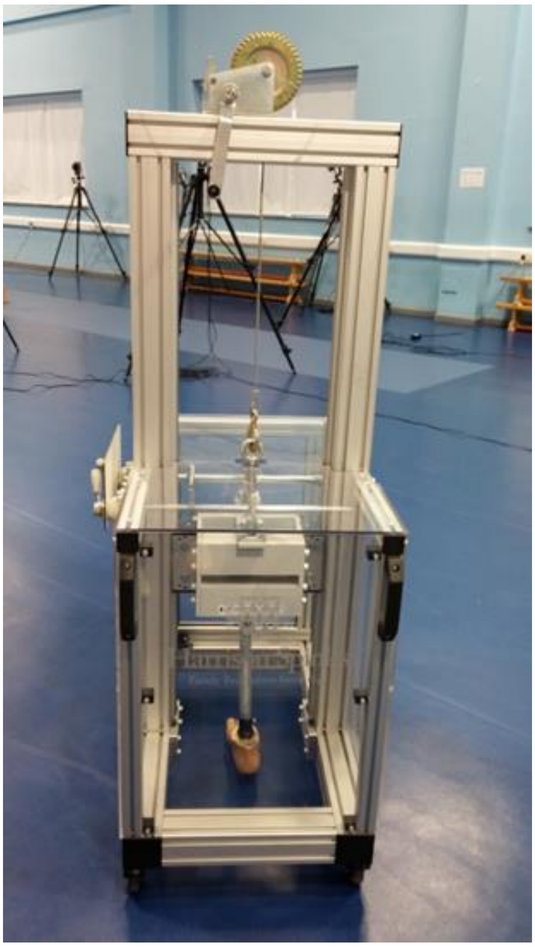

Figure 4-8: Drop rig test machine developed by engineers at Harrison Spinks Ltd

4.5 Sampling frequencies

When considering sampling frequencies, the faster the activity the greater the sampling frequency must be. Nyquist's sampling criterion states that the sampling rate must be at least twice the highest frequency component being measured in order to accurately reconstruct the signal, although this only gives the minimum usable sampling frequency (Antonsson and Mann 1985). Sampling frequency plays a critical role in providing an accurate and reproducible representation of the sampled signal.

The sampling frequency selected for the kinematic data in this project was 250Hz. When assessing running footwear and kinematics many other researchers have used this sampling frequency (Sinclair et al. 2012). It is also important to note that prior to motion capture the aperture of each camera was adjusted to aid focus and clarity of each retro-reflective marker.

It is accepted that when studying the frequency content of ground reaction forces during gait, in order to preserve 99% of the signal fidelity 15Hz must be maintained, requiring a minimum sampling frequency of 30Hz. Although if looking at heel strike impact this is likely to fall into the 1% rather than 99% of signal fidelity. The frequency content of take-off and landing in running is much higher, as a result higher sampling frequencies are generally chosen.

The sampling frequency selected for the kinetic data in this project was initially 2000Hz. When assessing running footwear and kinetics many other researchers have used a sampling frequency of between 1000Hz and 1500Hz. In order to explore the subtle and important variances between footwear iterations described in chapter 5 an increased sampling frequency was selected.

Towards the end of the prototype process outlined in chapter 5 the technical adjustments to the materials in the footwear were so miniscule, such as, increasing the midsole depth by a matter of millimetres and altering the spring wire diameter by a fraction of a millimetre, it was decided that the sampling frequency should to amplified further to look in real detail at the loading rate profile. The sampling frequency of the force platform was increased to 10,000Hz. To the authors knowledge, no other gait analysis study or footwear comparison exercise has sampled force platform data at this level. The repeatable nature of the drop rig tests, along with the increased sampling frequency offered the detail required to examine the nature of impact.

Tibial acceleration data throughout the project was obtained at 148Hz using the Delsys Trigno accelerometer sensor. Other recent studies comparing foot strike events using force plates and peak impact acceleration measures have used this sampling frequency (Whelan et al 2015). The accelerometer sensor used throughout data collection was limited to a maximum sampling frequency of 148Hz therefore there was no option to increase the sample rate.

Anti-aliasing was an important consideration for all data sets included in the project, that being the smoothing of output signals from all data collection devices. Filtering of data is often necessary in order to attenuate high frequency components in kinematic and kinetic signals, introduced through either soft tissue artefact, electrical interference, or improper digitisation of retro reflective markers. These errors are typically referred to as noise. All lab based kinetic data was subjected to a low-pass Butterworth 4th order filter with a 25 Hz cut-off frequency. All lab based kinematic data was filtered using a low-pass Butterworth 4th order filter at 6 Hz. Data from the accelerometer system collected through EMGworks (Delsys Inc., Boston, MA) was transferred to Visual3D (C-Motion., Germantown, MD) for eventing purposes. Analysis included calculating the ensemble mean of approximately 250 reps (footstrikes) per shoe condition (regular/P1.0's) per side (left/right). Although no specific smoothing technique was used on this data, the ensemble mean calculation simulated an anti-aliasing effect without direct application of a digital filter, thus preserving as much of the signal integrity as possible.

4.6 Knee pain questionnaires

4.6.1 Knee injury and osteoarthritis outcome score (KOOS)

There are a variety questionnaire tools currently used by clinicians and researchers to assess knee pain. The Knee Pain Screening Tool (KNEST), International Documentation Committee Subjective Knee Form (IKDC), Anterior Knee Pain Scale (AKPS), Oxford Knee Score are just a few. Each differs in what it looks to measure, who it is aimed at, recall period and design. The main reasons for selecting the KOOS questionnaire for this study were because it is designed for individuals with different forms of knee conditions, rather than focusing solely on a specific type of knee pain such as osteoarthritis, patellofemoral pain, or knee ligament injuries. In addition, the KOOS measures not only the general health of the knee, but also pain levels during sport and recreation activities, specifically running.

The KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire was developed in the 1990s as an instrument to assess the patient's opinion about their knee and associated problems. Since publication KOOS has been assessed by a number of studies. As part of a review into knee injury outcome measures, Wright (2009) notes KOOS makes possible a global assessment of recovery from knee injuries and clinician interventions. Garrett et al (2004) claim KOOS has good evidence for reliability, content validity and construct validity, along with evidence for responsiveness. KOOS has been used to examine knee pain in various recent studies. Sinclair (2016) found improvements were shown for Knee injury and Osteoarthritis Outcome Score subscales pain, sport, function and daily living when assessing the effects of a 10 week footstrike transition in habitual rearfoot runners with patellofemoral pain.

KOOS is a popular choice in clinical trials and is widely used for research purposes. KOOS has also been extensively used for clinical purposes to monitor groups and individuals over time. KOOS can be used over long and short term intervals to assess week by week changes and the influence of an intervention. The questionnaire consists of five subscales; pain, other symptoms, function in daily living, function in sport and recreation, and knee related quality of life. The previous week is the time period considered when answering the questions. Standardised answer options are given in the form of five likert boxes and each question is assigned a score from 0 to 4. A normalized score, 100 indicating no symptoms and 0 indicating extreme symptoms, is calculated for each subscale.

The five individual KOOS subscale scores can be given as secondary outcomes to enable clinical interpretation. An example of the KOOS questionnaire can be seen in appendix C. The ability of KOOS to differentiate sport from general daily life with respect to knee pain questioning makes it an ideal tool for this study. The Minimal Important Change (MIC) for the KOOS questionnaire is currently suggested to be 8-10 (Roos and Lohmander, 2003). However, the current understanding is that MIC is dependent on factors such as patient group, intervention and time to follow-up. Monticone et al (2013) suggested the minimal important changes for the sport and recreation subscale is 12.5.

Chapter 6 explores the effectiveness of micro spring technology to reduce reported pain in individuals who suffer from knee pain but still participate in recreational running.

Participants with knee pain were asked to complete the KOOS questionnaire prior to a 6 week intervention with the micro spring shoes and then again at the end of the intervention. Outcome scores were then compared and analysed, see chapter 6 for further details.

4.6.2 Numeric pain rating scale (NPRS)

A Numeric Pain Rating Scale (NPRS) was also used to evaluate levels of knee pain immediately post running trials in different footwear. Participants with knee pain were asked to complete the NPRS straight after completing five on road running reps in each trainer both before a 6 week intervention with the micro spring shoes and after, see chapter 6 for further details. The NPRS is an 11 point scale from 0-10 with 0 equalling no pain and 10 equalling intense pain. The scale is typically set up on a horizontal or vertical line and can be administered in written or verbal form. The patient is asked to rate his/her pain intensity and a particular time frame or descriptor is established. An example of the NPRS can be seen in appendix D.

Williamson & Hoggart (2005) suggested the NPRS has good sensitivity while producing data that can be statistically analysed. The NPRS scores high on ease of administration and simplicity for scoring (Jensen et al, 1986). The test-retest reliability for the NPRS has been demonstrated to be moderate to high, varying from 0.67 to 0.96 (Kahl and Cleland, 2005) and, when correlated with the Visual Analogue Scale (VAS), the NPRS is determined to have 0.79 to 0.95 convergent validity (Good et al, 2001). Convergent validity indicates that two measures assessing the same phenomenon measure the same construct, and yield similar results. Finch et al (2002) reports that a 3 point change in the NPRS is necessary to demonstrate a true change in pain intensity, implying that there are limitations in the responsiveness of a 0–10 scale.

However, in 2009, Piva, Gil and Fitzgerald explored responsiveness of the numeric pain rating scale in patients with patellofemoral pain and found a 1 point decrease on the NPRS seems to represent the minimum clinically meaningful improvement in this measure. They also suggest information from the NPRS can be used to evaluate the effectiveness of rehabilitation intervention on physical function and pain and to power future clinical trials on patients with patellofemoral pain.

4.6.3 Comfort

The comfort questionnaire used throughout this research could be classed as a Numeric Comfort Rating Scale (NCRS) as it was a modified version of a Numeric Pain Rating Scale (NPRS). All participants within the chapter 6 studies were asked to complete the NCRS straight after completing five on road running reps in each trainer. After trials, the runner rated three aspects of the shoe related to its comfort perceived. The comfort scale used a horizontal length with the left end labelled 'not comfortable at all' (0 comfort point) and the right end 'most comfortable condition imaginable' (10 comfort points). Since many aspects of footwear may influence comfort, specific comfort ratings were included: forefoot cushioning, heel cushioning, and overall comfort. An example of the comfort questionnaire can be seen in appendix E.

Comfort questionnaires used in other running related studies have taken a variety of forms. Most are often adapted and use a numeric rating system. In an experiment to investigate the effect of foot strike on comfort in running, Delgado et al (2013) used a comfort questionnaire selected and adapted from The Physical Activity Enjoyment Scale. The questionnaire was based on a seven-point scale with 1 and 7 being opposite extremes and 4 being neutral.

Other studies have used Visual Analogue Scales (VAS) to assess comfort when running. Lucas-Cuevas et al (2014) used a 150mm visual analogue scale (VAS) labelled at the left end as "not comfortable at all" (0 comfort points) and at the right end as "most comfortable condition imaginable" (15 comfort points). The following comfort variables were analysed: overall comfort, heel cushioning, forefoot cushioning, medio-lateral control, arch height, heel cup fit, shoe heel width, shoe forefoot width, and shoe length.

Although numeric rating scales offer quantifiable data in a format designed for statistical analysis, they do not provide qualitative information as to the comfort of a particular condition.

4.7 Statistical analysis

Kinematic and kinetic data recorded from the motion capture system and force plates were exported from Qualisys Track Manager in C3D format. Data files were imported into Visual 3D (Version 5.02.30, C-Motion Inc., USA) to be processed.

Two key normalisation techniques were employed in chapter 5. The first of these refers to normalisation of the parameters relating to ground reaction forces. This was carried out by dividing the recorded forces by each participant's body weight in newtons to allow forces to be reported in body weights per second. The second normalisation technique saw all time dependant data normalised between events established using Visual 3D. For the human based trials, the events were heel strike to toe off, for the drop rig trails, the events were initial impact to peak force. Data was normalised to 101 data points using a linear interpolation technique. This method was also used in chapter 6.

All kinematic and kinetic data was initially processed in Visual 3D, with mean and standard deviation information exported in ASCII file format and imported into Microsoft Excel for further analysis. In most instances maximum, minimum and range values were extracted for each parameter, subject and footwear condition before being transferred into IBM SPSS statistics 23 to run statistical calculations.

For each study described in this work, descriptive statistics of means and standard deviations were used to report outcome measures. With regards to inferential statistical analyses, statistical significance was accepted at the ≤ 0.05 level.

Details of specific statistical analysis run on each data set can be found in later chapters. In general terms, the analysis in chapter 5 was split between running repeated measures ANOVA's with post hoc pairwise comparisons on the human running studies and one way ANOVA's with post hoc pairwise comparisons on the drop rig data. The majority of the biomechanical analysis in chapter 6 involved a general linear model two factor repeated measures ANOVA with post hoc pairwise comparisons in SPSS. The comfort and pain analysis in chapter 6 involved running paired sample t-tests in Microsoft Excel.

CHAPTER 5: EXPLORING AN ENHANCED MASS-SPRING-DAMPER ARRANGEMENT WITHIN SPORTS FOOTWEAR

In order to begin the exploration into an enhanced mass-spring-damper arrangement within running shoes a number of developmental stages and a program of scientific testing was undertaken. Figure 5-1 shows the development flow diagram outlining the various stages of the process.

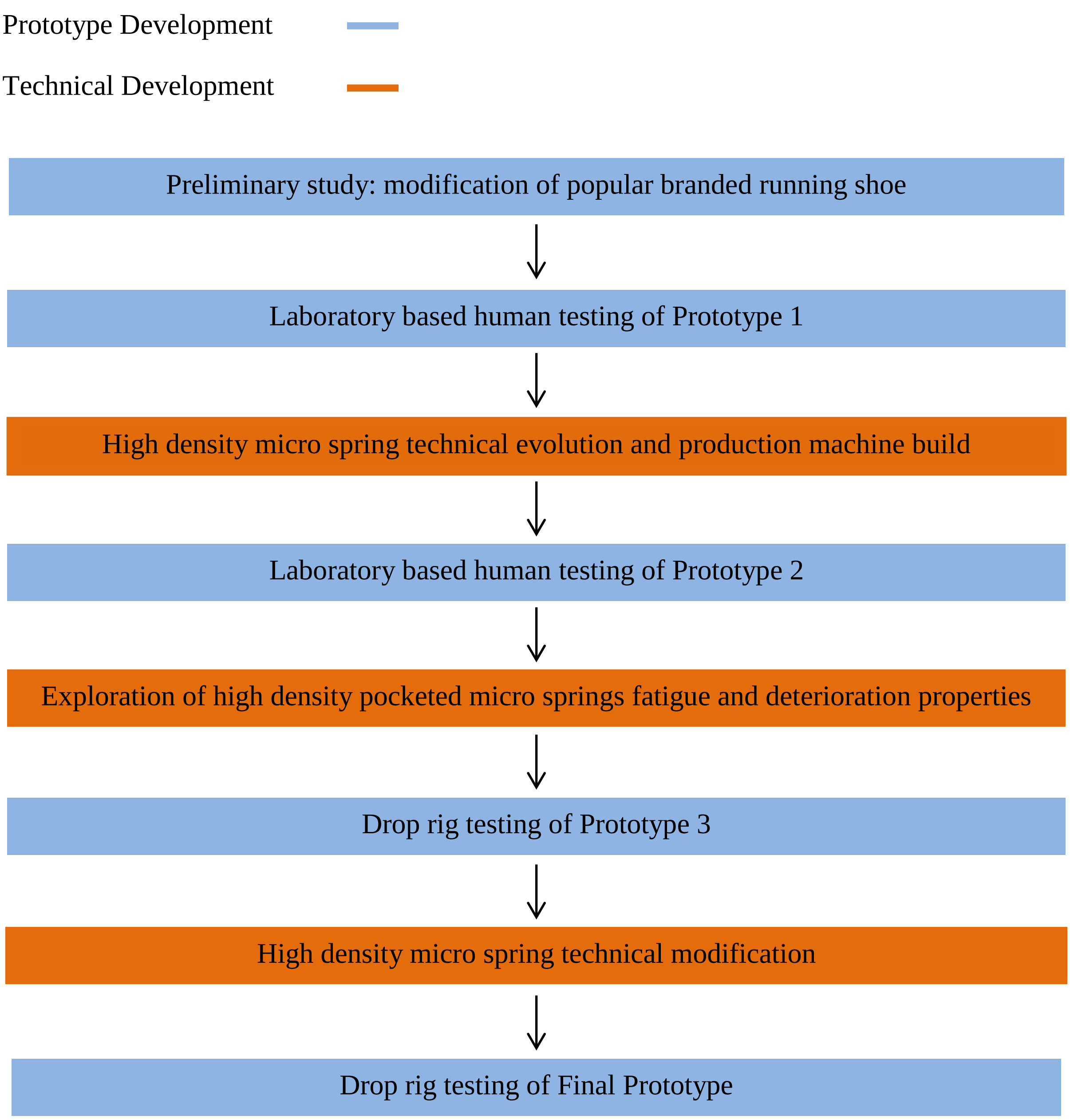

Figure 5-1: Development flow diagram

5.1 Preliminary study: modification of popular branded running shoe

5.1.1 Introduction

In order to explore the hypothesis that pocketed micro spring technology could have an influence on reducing impact loading properties in running shoes it was first necessary to consider possible spring configurations within the footwear. The preliminary study explored the biomechanics of running using two versions of a popular branded running shoe; one pair remained unmodified and the other was modified with 33 high density pocketed micro springs, at this time this was prototype technology developed by Harrison Spinks on existing spring production machinery. The pocketed micro springs were integrated into an existing commercially available running shoe by creating forefoot and rearfoot cavities in the shoe midsole using a specially modified dremel drill to remove foam based midsole material. The springs were secured in position with the use of adhesive and the shoe insole. The spring configuration was a matrix of 3x6 in the front of the shoe and 3x5 in the rear of the shoe. Care was taken that when the insole was replaced the micro springs were not visible and the shoes appeared virtually identical apart from a small sewn incision along the dorsal aspect of the forefoot of the modified shoe.

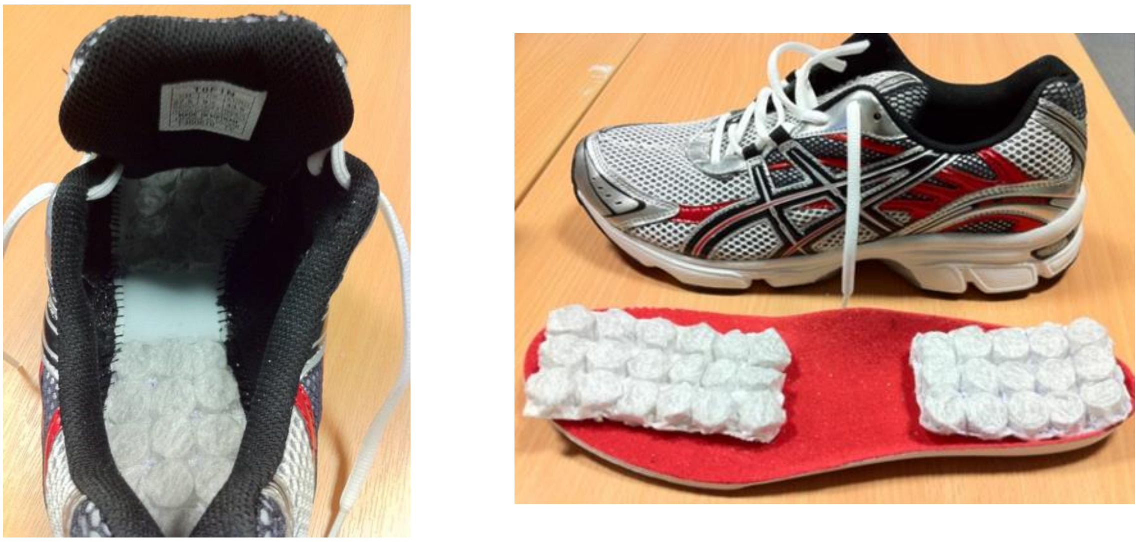

Figure 5-2: Popular branded running shoe modified with high density pocketed micro springs

As identified in the literature review, impact loading of the lower extremity plays a key role in a number of common running related injuries. Researchers have examined interventions that use materials designed to cushion impacts to reduce stress fractures, knee pain and medial tibial stress syndrome, suggesting it is likely that impact forces play an important role in causing running injuries (Crowell et al 2010). Impact and running has been an acknowledged area of focus by researchers such as Davis and Hamill. In a prospective study of runners, Davis et al (2004) collected a variety of biomechanical measures from a large group of runners and found a positive correlation between higher peak positive acceleration of the tibia and vertical-force loading rates and injury incidence.

The preliminary study aimed to investigate potential changes in the vertical loading rate parameter through the introduction of pocketed micro springs into running shoes. In most studies loading rate values are represented in the form of body weights per second. The calculation used to quantify this value was achieved by dividing the recorded force loading rates by each participant's body weight in Newtons.

5.1.2 Methods

Three-dimensional kinematics and kinetics were recorded from 11 healthy recreational heel strike runners during over ground running in the Movement Analysis Laboratory at the University of Central Lancashire (UCLan). Specifics of equipment used and motion capture set up can be found in chapter 4. Test conditions were single blinded and randomised. Each subject was asked to complete five running trials of approximately 20 metres under each test condition (non-modified and modified) at a self-selected speed. The methodology for calculation of average vertical loading rate was done over the middle 60% of the vertical ground reaction force curve from foot strike to the vertical impact peak. A paired t-test was conducted to determine the differences in loading rate between the two conditions.

5.1.3 Results

No significant differences were seen in the peak vertical ground reaction force, the anterior push off force or the contact time between the two shoe configurations. However, the introduction of the high density micro-springs showed a significant reduction in the average vertical loading rate of 10.4 body weights per second or 11.5% in the modified shoe compared with the unmodified shoe, see figure 5-4. This was confirmed statistically with a significant difference of p=0.005 which can be considered highly significant.

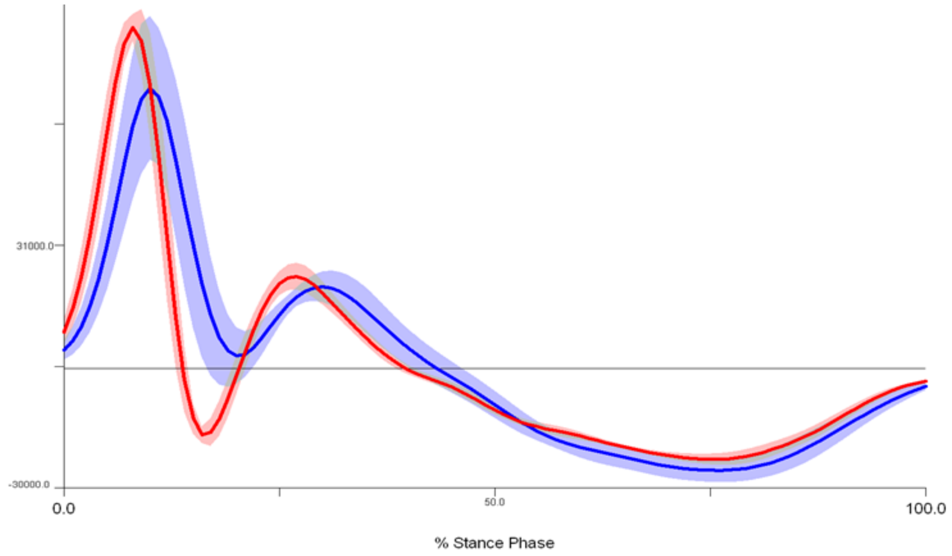

Figure 5-3: Loading rate comparison of non-modified (red line) and modified (blue line) running shoe

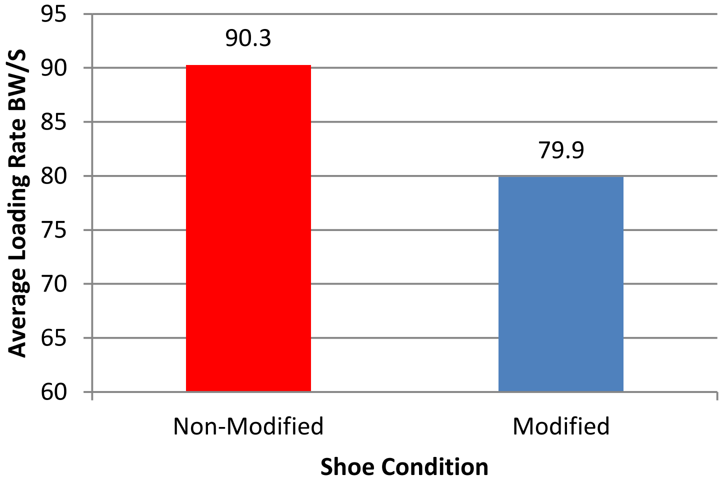

Figure 5-4: Vertical loading rate reduction of shoe modified with pocketed micro springs

In addition to the vertical loading rate, the peak posterior ground reaction force showed a significantly lower force of -0.374 N/BW with the modified shoes with integrated pocketed micro spring technology compared to -0.418 N/BW for the unmodified shoes. This was a significant reduction 10.5% (p=0.002), see figures 5-5 and 5-6.

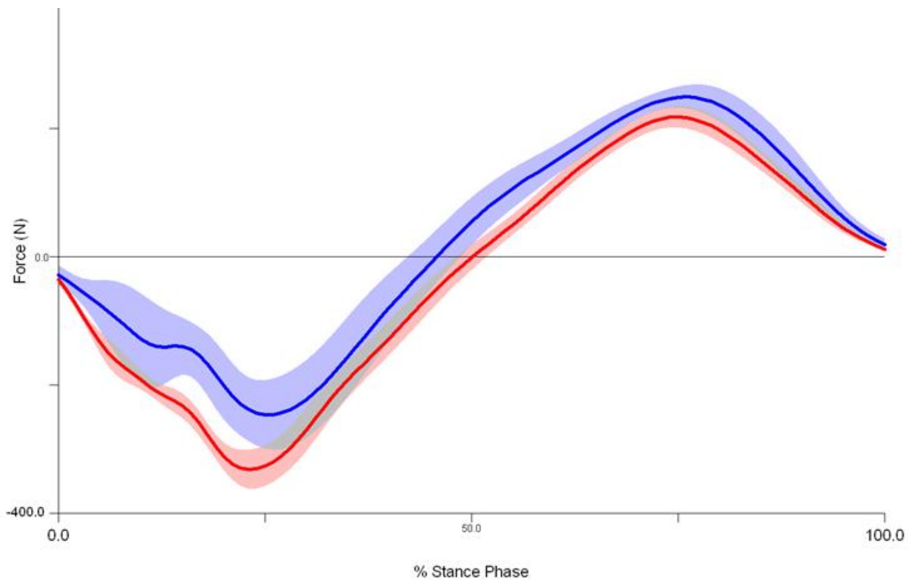

Figure 5-5: Posterior GRF comparison of non-modified (red line) and modified (blue line) running shoe

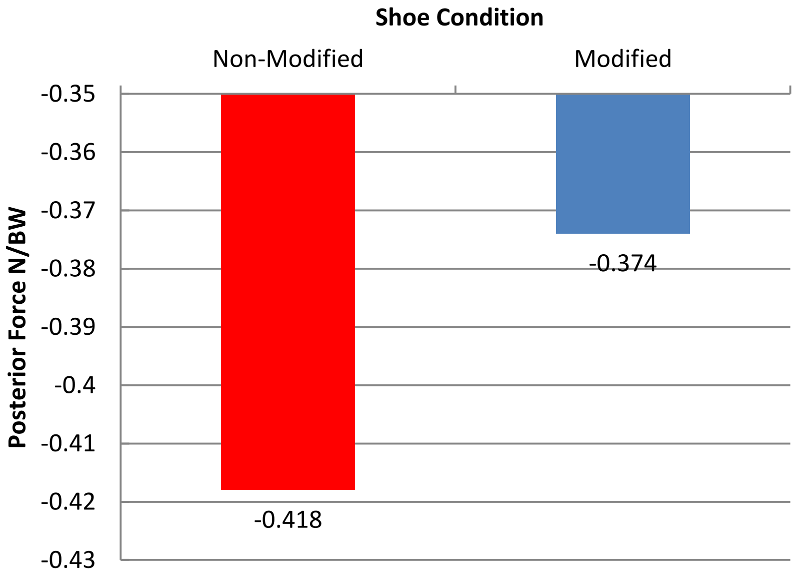

Figure 5-6: Posterior GRF reduction of shoe modified with pocketed micro springs

5.1.4 Discussion

The similarity in the contact time and the peak vertical loading force of the non-modified and modified running shoes indicated similar propulsion performance and running speed. The results of this preliminary study support the findings of Davis et al (2010) that it is loading rate that is the key variable to assess rather than peak force when it comes to exploring injury. At this stage, subjective verbal feedback from participants was largely positive with an increase in perceived comfort levels when running in the modified shoes.

Shoe midsole hardness is an area of research that has had particular attention with regards to running injury. Nigg et al (1987) found that midsole hardness does not influence magnitude and loading rate of the external vertical impact forces. However, more recent studies such as Baltich et al (2015), confirm that shoe midsole hardness can have an effect on vertical impact force peaks and that this may be connected to the hardness of the landing. Such results may provide useful information regarding the development of cushioning guidelines for running shoes. It might be argued that the additional cushioning in the highly-cushioned shoes should reduce the shock experienced by the lower extremity. However, it has been shown that individuals tend to stiffen their leg when landing on soft surfaces. A stiffer leg during landing is not likely to attenuate shock as well as a compliant one. This will result in greater shock experienced by the leg (Ruder et el. 2015). Therefore, careful consideration was given to the relationship between the springs and damper material when progressing with the development of the first prototype.

5.1.5 Conclusions

The significant reductions in the average vertical loading rate and the peak posterior forces found in the modified shoe with the high density pocketed micro spring technology could provide clinically important differences which could help runners who report overuse running injuries.

5.2 Laboratory based human testing of Prototype 1

5.2.1 Introduction

With initial positive results of the efficacy of the new technology, thoughts turned to other contributing factors likely to influence the enhancement of a mass-spring-damper arrangement within running shoes. The balance between the spring stiffness and surrounding damper materials of the sole was thought worthy of further exploration. This led to the introduction of the high density pocketed micro springs into a purpose-built prototype, designed specifically to accommodate the high density pocketed micro spring technology into the midsole of the running shoe. Many other researchers (Clarke el al., 1983, Aguinaldo and Mahar., 2003) have previously shown that even in similar shoe types, vertical loading rate values can vary significantly with different midsole cushioning constructions.

Figure 5-7: The first prototype developed by Intersport IC

The prototype integrated the same pocketed high density micro springs used in the preliminary study. At this time, these were pocketed by hand by the engineering team at Harrison Spinks as the development machine did not have this capability. These original micro springs were straight in design, 10mm in height, made from 1.4mm cylindrical steel wire and encased in polypropylene non-woven fabric heat welded by hand to form pockets. The first prototype was designed with a forefoot and rearfoot cavity pre-moulded into the shoe midsole to accommodate the springs. Springs were not included under the midfoot arch as concerns were raised as to the midsole's ability to maintain its structural integrity with an extra cavity. The configuration housed within the prototype therefore was 3x3+2 in the forefoot cavity and 3x2 in the rearfoot cavity see figure 5-8. This was the maximum number of pocketed micro springs that was possible to be incorporated with the midsole tooling available for the shoe design. The aim of this study was to explore the effect of integrating springs into a purpose designed running shoe midsole.

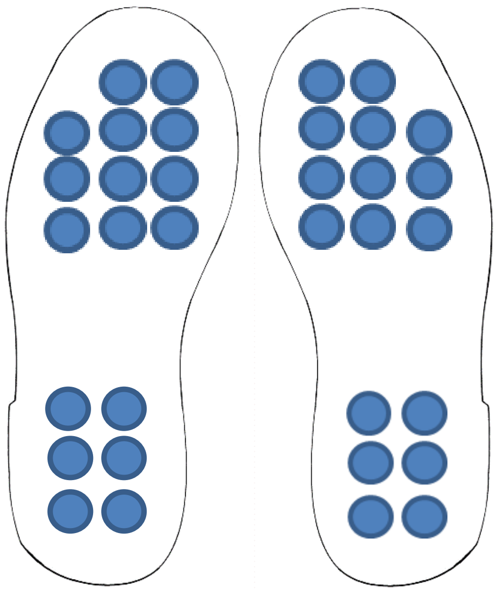

Figure 5-8: Spring matrix configuration in the first prototype

5.2.2 Methods

The first prototype was tested against two models of a popular branded running shoe, best sellers on the market at that time. Fourteen subjects were recruited to take part in over ground running trials in the Movement Analysis Laboratory at UCLan. Participants were recruited from a population of recreational runners which included staff and students at UCLan along with attendees of local running clubs. Participant recruitment was conducted by approaching the running clubs, with permission from the running club chairmen, and by poster recruitment /via email on site at UCLan.

A ten camera Qualisys movement analysis system and AMTI force plates, sampling at 2000Hz, were used. This is slightly in excess of the typical sampling frequency of between 1000Hz and 1500Hz used in other similar studies looking at running shoes and impact in order to explore the subtle and important variances between footwear iterations.

The model used in laboratory running trials throughout this project was a three-segment foot model, with markers placed on the shoe and not the foot itself. This model allows analysis in six degrees of freedom between three segments of the foot. The protocol mirrored that of the preliminary study, with each subject completing 5 running trials of approximately 20 metres under each test condition at a self-selected speed. GRF and loading rate values were represented in the form of body weights per second. A repeated measures ANOVA was conducted to determine the changes in loading rate between the conditions with a pairwise comparison using least significant difference method for multiple comparisons.

5.2.3 Results

No significant differences were observed in peak vertical ground reaction force (p=0.154). All three shoes were seen to have very similar patterns with no significant differences identified between peak values, see table 5-1.

Table 5-1: Descriptive statistics of peak vertical GRF results for laboratory based human testing of first prototype

	Mean BW/s (SD)
Model 1	2.45 (0.20)
Model 2	2.43 (0.21)
Prototype 1	2.41 (0.20)

Grouped analysis showed no significant differences with respect to average vertical loading rate between the first prototype purpose built to integrate the high density micro spring technology and the two popular branded running shoes. Although the first prototype demonstrated a 5.8% reduction in average vertical loading rate compared to model 1 of the popular branded running shoe, its average vertical loading rate was still 21.9% higher than model 2 of the popular branded running shoe. A significant difference with respect to average vertical loading rate was identified between model 1 and model 2 (p=0.025), see table 5-2.

Table 5-2: Pairwise comparisons and descriptive statistics of average vertical loading rate results for laboratory based human testing of first prototype

Comparison		**Mean Difference BW/s**	**p-Value**	**Confidence Interval of the difference (95%)**
Model 1	**Model 2**	23.86*	0.025*	4.05 to 43.67
Model 1	**Prototype 1**	15.92	0.168	-8.58 to 40.42
Model 2	**Prototype 1**	-7.94	0.227	-22.11 to 6.23

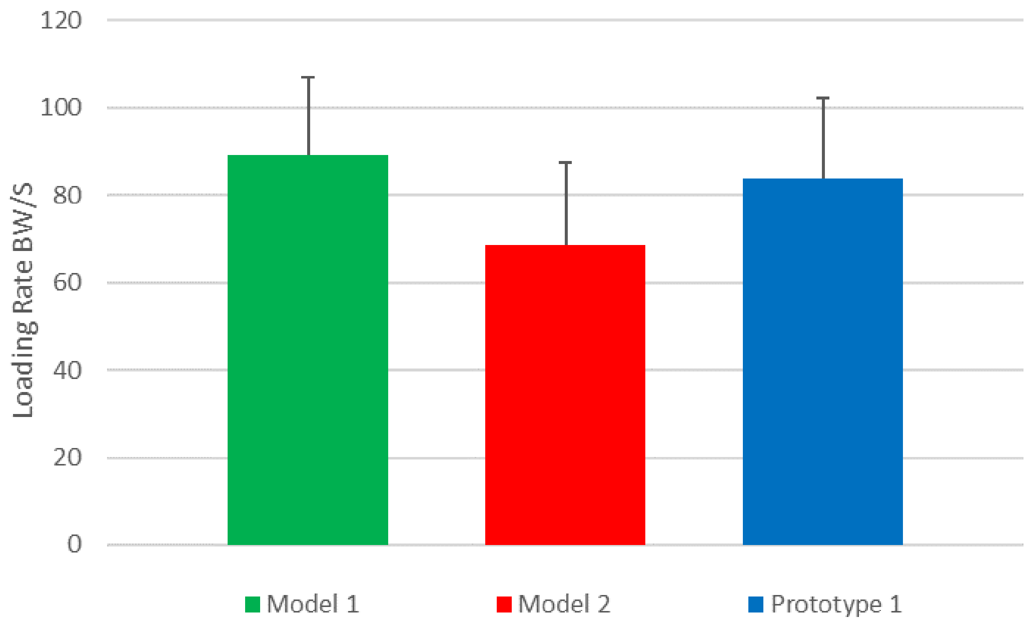

Figure 5-9: Vertical loading rate comparison between first prototype and two models of popular branded running shoe

5.2.4 Discussion

Comparative average vertical loading rate data to the competitors served as proof of concept for the integration of high density pocketed micro springs into a running shoe midsole. Although the results did not reach the significance levels of the preliminary study, the modified shoe tested was not practical nor commercially viable to manufacture. There are a number of possible explanations as to why the first prototype did not perform as well as the modified shoe from the preliminary study when compared to a popular branded running shoe. Firstly, the modified shoe contained significantly more micro spring in total than the first prototype. Prototype 1 was only able to accommodate 17 springs per shoe, whilst the modified shoe housed 33 springs per shoe, therefore having a higher spring density. Also, it is likely that the hardness of the midsole damper material was not comparable between the shoes which would be an influencing factor. Unfortunately, at this stage in the project a durometer was not available to confirm this assumption, therefore this statement was a suggestion based on the author's physical analysis of the shoes.

After discussions with the manufacturing team at Intersport IC's Vietnam based factory and the technical engineers at Harrison Spinks it was proposed that modifications to damper hardness chosen as part of the midsole design and to the micro spring itself could potentially see improvements in the capability of a finished product to better perform against market leading running shoes with respect to vertical loading rate. Considerations were taken how best to achieve a closer damper hardness/spring rate match to the modified shoe from the preliminary study when developing the second prototype. This provided a complex challenge as no other work exists on the relationship between micro springs and midsole dampers with respect to footwear design. The outcomes of lengthy development discussions are described in section 5.3.

5.2.5 Conclusions

A running shoe was designed that could perform in line with some of the bestselling running shoes currently available in the commercial market place. It was concluded that there was further scope to enhance the spring damper arrangement and a need for further exploration of the optimum spring rate/damper hardness shock absorbing configuration.

5.3 High density micro spring technical evolution and production machine build

Up to this point the high density pocketed micro springs were produced through a time consuming, labour intensive handmade process. The springs themselves were produced on a traditional CNC spring coiling machine with a maximum output of only 150 springs per minute. They were then individually placed into an outlined matrix on polypropylene non-woven fabric and enclosed using a handheld bar welder. The total time required to produce the four pocketed micro spring pads needed in one pair of running shoes was in excess of five minutes. In order to enhance the production and commercial viability of the high density pocketed micro spring technology, the Harrison Spinks engineering team designed and developed a pocketed high density micro spring production machine, integrating magnetic belts, drive mechanisms and ultrasonic welding, capable of producing an output of 300 pocket springs per minute. This significantly reduced the time required to produce the relevant matrix for one pair of running shoes to a matter of seconds. A technical testing programme described below assessed the reliability and reproducibility of the product and led to alterations in the high density micro springs.

In the first instance, the production machine was only capable of running 1.3mm cylindrical steel wire due to coiling point restrictions. As such there was a necessity to explore amendments to the spring geometry in an attempt to replicate the spring rate of the handmade 1.4mm spring. The design was modified from straight to conical, see figure 5-10. A conical design would allow a spring to retain the rate of a spring with a greater wire diameter without the need to adjust the height. With the depth of the prototype midsole moulds unable to be altered this was an important consideration.

Figure 5-10: Straight Spring Conical Spring

Spring rate and hysteresis analysis indicated that the 1.3mm machine run conical spring was comparative to the rate of the previous 1.4mm handmade straight spring, see table 5-3. This was achieved through alterations to the spring pitch (the distance between spring convolutions). Spring rate is the constant amount of force that is needed to compress a spring a certain distance. The hysteresis curve observes how much absorbed compression energy is returned through a compression cycle. The conical design also carried the added benefit of allowing each convolution of the spring to sit inside the previous, thus reducing any possible noise issues arising from metal on metal contact through compression. The number of active convolutions in a conical spring is also greater than in a straight spring, increasing the amount force that needs to be applied before the springs become coil bound. The result of this was a potential improvement in the spring/damper interaction as they are allowed to work in unison for more of the compression cycle.

Table 5-3: Spring rate comparison of 1.4mm straight spring and 1.3mm conical spring

1.4mm Straight Spring	5.090 N/mm
1.3mm Conical Spring	5.092 N/mm

The development of the conical design led to the question of which way up to house the pad of springs in the running shoe midsole. Compression rate tests identified no difference in spring rate between large coil up or small coil up, both gave values of 5.092 N/mm. However, this led to the further consideration of avoiding high pressure points through the insole onto the foot therefore, for the next prototype iteration the decision was made to sit the pocketed micro springs into the midsole large coil up, thus increasing the contact area with the sole of the foot with the view to providing improved user comfort.

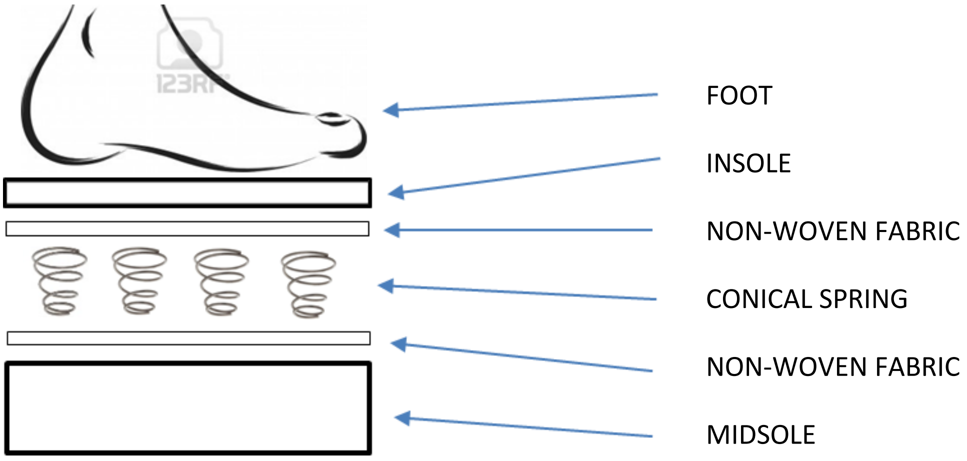

Figure 5-11: Pocketed micro spring positioning in second prototype

5.4 Laboratory based human testing of Prototype 2

5.4.1 Introduction

Throughout the prototype iteration process, Intersport IC used the name “Preston” as a model reference in appreciation of the role the University of Central Lancashire had played in the development of the micro spring running shoe project to date. The model name “Preston” also served to draw attention to the scientific nature of this development and the importance placed on the aim of eventually publishing the key findings in an academic domain. Intersport IC were keen to use pocketed micro spring technology as the unique selling point to relaunch their own brand of running shoe ProTouch. At this time, Intersport IC stocked all the major running shoe brands on the market, Adidas, Nike, Asics, Saucony, Brooks etc but their own brand ProTouch had been somewhat dormant for a few years and was not currently stocked in most of their European stores.

The second prototype developed by Intersport IC, see figure 5-12, saw the introduction of the machine run 1.3mm conical micro springs. No other adjustments were made to the midsole construction at this stage in order to focus on the effect of changing one variable at a time. However, the upper design was amended by Intersport IC’s Italian design team to explore different aesthetic options ahead of a potential product launch after testing and further developments were complete.

Figure 5-12: The second prototype

5.4.2 Methods

For this study, 10 participants were recruited and participated in testing. Again, participants were recruited from a population of recreational runners which included staff and students at UCLan along with attendees of local running clubs. Participant recruitment was conducted by approaching the running clubs, with permission from the running club chairmen, and by poster recruitment/via email on site at UCLan. As with the preliminary study and the testing of the first prototype, each subject completing 5 running trials of approximately 20 metres under each test condition at a self-selected speed. A ten camera Qualisys movement analysis system and AMTI force plates, sampling at 2000Hz was used, further reasoning and justification is outlined in the general methods chapter 4.

Prototype 2 was tested against the same two market leading running shoes as the first prototype. In each laboratory based study, participants received a participation information sheet that provided information regarding what is involved in taking part in the study. Each participant was asked to complete a health screening questionnaire, see appendix H, to ensure that the inclusion criteria was met and a consent form, see appendix B, was signed and witnessed prior to commencement of testing. Details of project ethical approval can be seen in appendix A. A repeated measures ANOVA was conducted to determine the changes in loading rate between the conditions with a pairwise comparison using least significant difference method for multiple comparisons.

In addition to investigating potential differences in average vertical loading rate, this study also explored the concept of instantaneous vertical loading rate, although this variable was approached in a different manner to previous definitions of this variable in the wider literature. Instantaneous vertical loading rate has previously been defined as the maximum slope of the vertical ground reaction force curve between successive data points in the region from 20% of the vertical impact peak to 80% of the vertical impact peak (Crowell and Davis 2011). However, from in depth individual analysis of impact profiles from subjects in the previous studies, it was clear that some important variances appeared to be taking place specifically within the first 5% of the stance phase. For example, subjects with very similar average vertical loading rates showed significantly different vertical loading rates immediately after impact, at around 5% of the stance phase.

Although the typical vertical impact peak of a rearfoot strike runner occurs somewhere between 15-25% of stance phase, this research took a closer look at the first 5% of stance phase. As such, for this study and throughout the remainder of the project the maximum slope of the vertical ground reaction force curve between first contact and 5% of stance was identified as a biomechanical parameter of particular interest. In order to consistently identify the first 5% of vertical impact stance phase for each participant, all data was normalised to 101 data points within Visual 3-D using a linear interpolation technique. It was acknowledged that exploring the initial 5% of stance phase meant a focus on the relatively small number of data points available in this short timescale, this is discussed further in the limitations section at the end of the thesis.

5.4.3 Results

As was the case with the first prototype, no significant differences were seen in the average vertical loading rate between the second prototype and the two models of popular branded running shoes. However, unlike the results from the laboratory based human testing of the first prototype whereby, the first prototype demonstrated a 5.8% reduction in average vertical loading rate compared to model 1 of the popular branded running shoe, in this study, the second prototype had a higher average vertical loading rate than both models of the popular branded running shoe, see table 5-4 below.

Table 5-4: Descriptive statistics of average vertical loading rate results for laboratory based human testing of second prototype

	Mean BW/s (SD)
Model 1	66.27 (25.48)
Model 2	72.26 (22.993)
Prototype 2	75.09 (27.037)

Yet, the second prototype (integrating machine run 1.3mm conical pocketed micro springs) did show a significant reduction in initial vertical loading rate of 5.4 body weights per second compared with model one of the popular branded running shoes within the first 5% of the stance phase, equivalent to a 14.3% reduction. Analysis showed no significant differences with respect to initial vertical loading rate at 5% of impact stance between Prototype 2 and model two of the popular branded running shoe, see table 5-5.

Table 5-5: Pairwise comparisons and descriptive statistics of initial vertical loading rate results at 5% of stance phase for laboratory based human testing of second prototype

Comparison		Mean Difference BW/s	p-Value	Confidence Interval of the difference (95%)
Model 1	**Model 2**	4.51	0.388	-7.77 to 16.80
Model 1	**Prototype 2**	6.45*	0.041*	0.37 to 12.52
Model 2	**Prototype 2**	1.93	0.557	-5.98 to 9.85

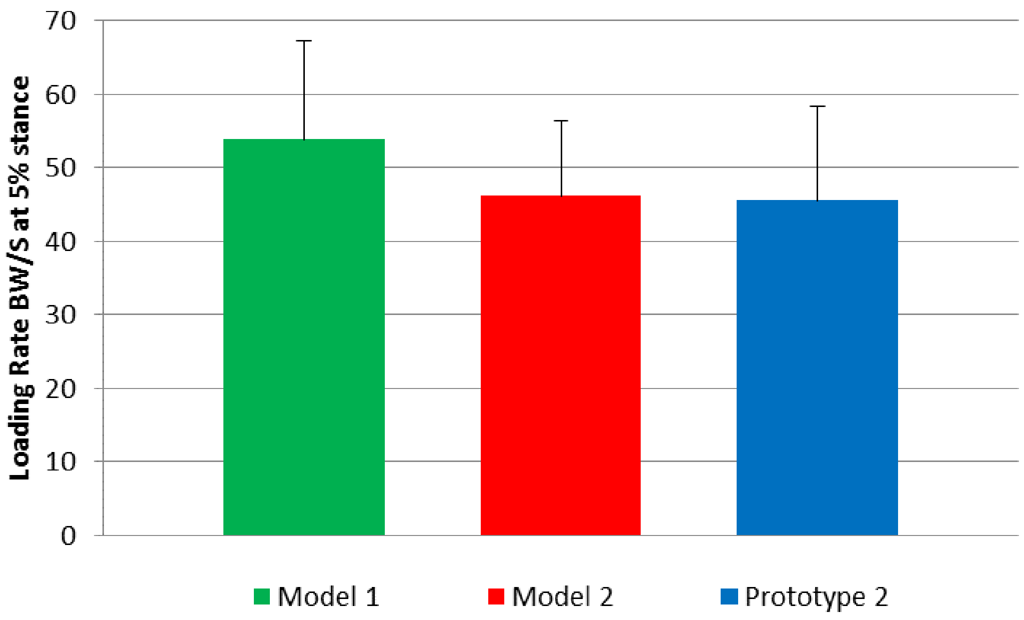

Figure 5-13: Initial vertical loading rate comparison between second prototype and two models of popular branded running shoe at 5% of stance phase

5.4.4 Discussion

Identifying the discrepancy in loading rate performance at various stages of the contact phase served to demonstrate the subtleties involved in human testing and the scope of analysis needed to comprehensively assess the effectiveness of the mass-spring-damper arrangement.

Other studies support the notion that instantaneous vertical loading rate as a principal is an important phase of impact to investigate when exploring running injuries and shock absorption. A prospective report by Davis et al (2004) concluded runners who developed injuries had higher instantaneous vertical ground reaction force loading rates than a group of age and mileage matched control subjects. Similarly, in a number of retrospective studies, subjects who had sustained a stress fracture had higher average and instantaneous vertical ground reaction force loading rates (Pohl et al 2008, Creaby and Dixon 2008). These previous findings add weight to the argument that shock absorption performance within the early stages of impact could point towards effectiveness of injury reduction properties. To the authors knowledge, there are no published findings with respect to specifically the first 5% of stance phase. Whilst recognising the relevance of peak loading rate as an important measure, a more detailed exploration of this principle, within a more specific timeframe, was thought worth of further investigation. Evaluating technology performance at this level of detail became the driver and justification for methods chosen to assess the next prototype iterations.

The question remained as to the clinical importance of such reductions of loading rate with respect to injury risk and pain. Although the pocketed micro spring technology had been seen to provide significant reductions in initial impact loading rate at 5% of the stance phase when compared to a popular branded running shoe, would this have a bearing on the likelihood of a runner sustaining an injury.

When considering previous studies, researchers have reported varying loading rate discrepancies between control groups and injured runners. Hreljac et al (2000) reported a difference of 16.5 BW/s between an injured group and non-injured group of runners with respect to maximal vertical loading rate. Biomechanical data showed a significant difference in mean maximal vertical loading rate of 93.1 ± 23.8 BW/s for the injured group and 76.6 ± 19.5 BW/s for the non-injured group ($p=0.001$). This was supported by the findings of Milner et al (2006) who found a significant difference of 12.91 BW/s in vertical initial loading rate between an injured group and non-injured group of runners ($p=0.036$). With a mean vertical initial loading rate of 92.56 ± 24.74 BW/s for the injured group compared to 79.65 ± 18.81 BW/s for the non-injured group. They also identified a significant difference of 12.66 BW/s between an injured group and non-injured group of runners with respect to vertical average loading rate ($p=0.041$). With a mean vertical average loading rate of 78.97 ± 24.96 BW/s for the injured group and 66.31 ± 19.52 BW/s for the non-injured group. In both studies, vertical impact peaks were also measured but demonstrated no significant differences between injured and non injured groups, further supporting the hypothesis that impact loading rate is a more valid indicator of injury risk.

In a systematic review of the literature Zadpoor and Nikooyan (2011) established that of the 13 selected articles, all showed higher average vertical loading rate values and initial vertical loading rate values in the injured group compared to the control group of runners. Not all exhibited significant differences between the two groups but all did demonstrate the same trend. The relationship between loading rate reductions and injury is explored in detail in chapter 6.

5.4.5 Conclusions

The results suggest that the technical amendments made to the pocketed high density micro springs prior to prototype two led to significant differences demonstrated between prototype two and one of the market leading popular branded running shoes with respect to initial vertical loading rate within the first 5% of the stance phase.

5.5 Exploration of high density pocketed micro springs fatigue and deterioration properties

Durability of any potentially commercial product is important. Running shoe technology is expected to withstand repetitive high levels of loading over an extended period of time with recent advice stating running shoes should be changed every 500 miles due to deterioration of component parts. Regular commercial footwear testing focuses largely on testing shoes as a finished product with durability, sole grip strength and impact properties regularly evaluated during the design process. As the pocketed micro spring technology was a new innovation to the footwear market it seemed prudent to ensure the single component was tested to its limits.

Fatigue tests, conducted on a bespoke custom made durability rig, designed and manufactured by the author in conjunction with the Harrison Spinks engineering team, established that the high density pocketed micro springs were able to withstand more than one million compression cycles without failure. The durability rig consisted of two regular stainless steel plates 10mm in depth and 100mm square, one fixed and the other driven by a pneumatic press device, see figure 15-4. The rig was designed to compress the pocketed micro spring to 80% of full compression. An automated counter was attached to the rig to count the number of compression cycles.

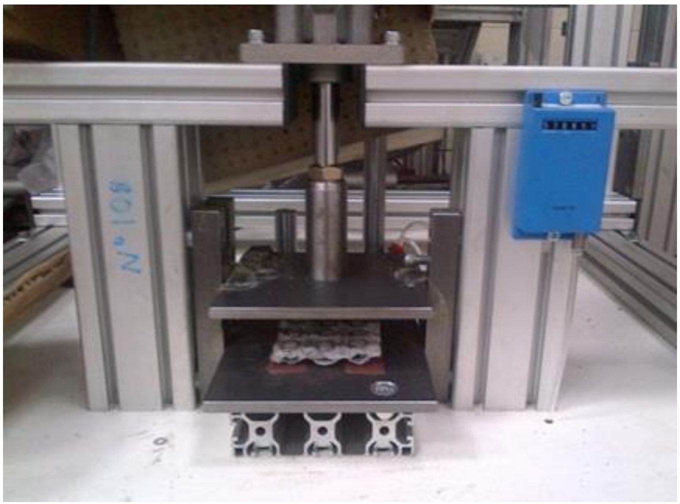

Figure 5-14: Fatigue test of high density pocketed micro springs

Hysteresis analysis, conducted on an industrial compression machine, suggested that the micro springs showed no deterioration or fatiguing of their material properties or characteristics after the test. Below is the hysteresis curve of the micro spring technology after one million compression cycles, see figure 5-15, this is near identical to the hysteresis curve of the technology prior to the durability test. Hysteresis relates to the dependence of a product under deformation. The area within the centre of the hysteresis loop is the energy dissipated. Pocketed micro springs have an extremely shallow hysteresis loop demonstrating that almost no mechanical energy is lost through a compression cycle. In other words, micro springs have significant mechanical energy return properties.

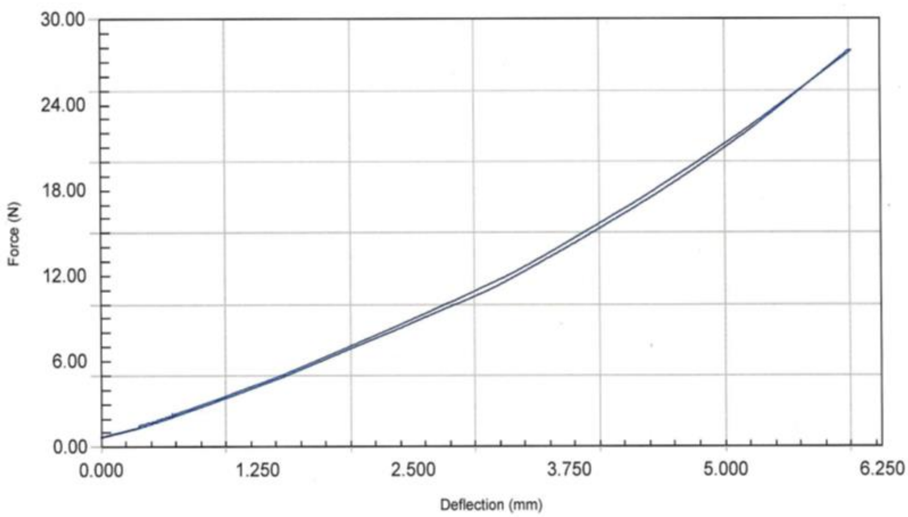

Figure 5-15: Hysteresis curve of pocketed micro springs after one million compression cycles

The springs were also subjected to an independent ISO IEC 17025 (UKAS) accredited technical spring rate assessment at the Institute of Spring Technology (IST) in Sheffield, the UK's International Independent Centre of Excellence for Spring Technology (see appendix F). The pocketed micro springs were subjected to the rigorous British Standard 1726-1 test procedure whereby springs are tested at 20% and 80% of the safe deflection from the nominal free length of the spring, and then the spring rate recorded as a N/mm value. With a spring rate of 5.092 N/mm it was concluded the technology was capable of performing consistently under repetitive high impact loads.

As the micro springs are contained within footwear, an understanding of how the technology reacts to varied temperature and moisture conditions is vital. A corrosion test comparing regular steel wire to galvanised wire was conducted to evaluate which would be the most suitable wire coating. Galvanisation is the process of applying a protective zinc coating to steel or iron, to prevent rusting. The most common method is hot-dip galvanising, in which parts are submerged in a bath of molten zinc.

Figure 5-16: Regular steel wire sample post salt spray test

Figure 5-17: Galvanised steel wire sample post salt spray test

Galvanised and non-galvanised samples were subjected to a prolonged salt spray test. Each sample was sprayed with 5ml of a sodium chloride solution each day for one full week. Both samples were then completely submerged in the solution for 6 weeks. Corrosion became visible within 2 days on the regular steel wire whereas, galvanised wire corrosion only became apparent after 6 weeks of complete submersion in a salt water bath. The decision to use galvanised steel wire in all future iterations was confirmed at this stage.

5.6 Drop rig testing of Prototype 3

5.6.1 Introduction

One of the challenges in footwear testing is determining the effects of subtle differences in the design and materials used in running shoes; this is due to intra and inter subject variability in human running trials. As development of the prototype running shoes continued it became increasingly challenging to evaluate the minor changes made to each iteration using human participants. To resolve this issue a new drop rig testing machine was developed by the author and Harrison Spinks engineering team that could replicate both rearfoot and forefoot impact loading during running. For design details, refer back to chapter 4.4

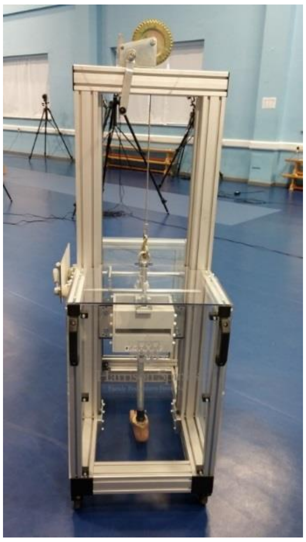

Figure 5-18: Drop rig testing machine

The drop rig was used to explore the differences in loading properties between the two popular models of running shoe used in human trials, along with the most recent third prototype which incorporated a new upper design. The hardness of the EVA foam midsole was also changed for the third prototype from 45^0 to 55^0 as measured with an Asker C Scale Durometer to bring it closer in line with hardness of the EVA foam used in the two popular models of running shoe tested against, which were 55^0 and 58^0 respectively. Discussions were had with the factory responsible for producing the prototypes as to the scope available to vary foam hardness, however selections were limited to EVA foam harnesses the factory had available at the time of production and cost/time restraints.

Hardness may be defined as a material's resistance to indentation. Durometer is one of several measures of the hardness of a material. Higher numbers indicate harder materials; lower numbers indicate softer materials. There are several scales of durometer, used for materials with different properties. The two most common scales, using slightly different measurement systems, are the Asker C Scale and the Shore A Scale. Durometer, like many other hardness tests, measures the depth of an indentation in the material created by a given force on a standardized presser foot. The basic test requires applying the force in a consistent manner, without shock, and measuring the hardness (depth of the indentation). Midsoles of the shoes were all made from closed cell foam, the most common of which is EVA (ethyl vinyl acetate). EVA is light weight, durable, easy to form and resists compression set. It is available in a wide range of densities and formulations.

5.6.2 Methods

As was the case with the human studies, force analysis was conducted using an AMTI BP400600 force platform in the Movement Analysis Laboratory at UCLan. However, rather than sampling at 2000Hz, as with the human trials, the decision was made to sample at 10,000 Hz. The decision to increase the sampling frequency stemmed from the need to look in closer detail at the loading rate profile given the technical adjustments to the materials in the footwear were so subtle at this stage.

To the authors knowledge, no other gait analysis study or footwear comparison exercise has sampled force platform data at this rate. The repeatable nature of the drop rig tests, along with the increased sampling frequency, allowed an examination of the nature of the impacts in greater detail than has been previously reported in the literature. As the drop rig trials consisted of vertical drops rather than the forward locomotion data collected in human trials, loading rate was assessed from point of first impact through to peak force.

The three shoes tested were mounted onto the drop rig via the multiflex prosthetic foot and secured by tying the shoe laces tightly. The shoes were dropped directly onto a force platform 20 times on the forefoot and 20 times on the rearfoot. The drop rig mechanism was controlled by a double handle manual release. To return the drop rig to its start position before each trial a circular crank shaft was operated. Prior to each drop trial, the 10mm drop height was checked and verified using a custom made measuring device. The differences in loading properties between the shoes were assessed using a one way ANOVA with post hoc pairwise comparison.

Figure 5-19: The third prototype

5.6.3 Results

The addition of an enhanced spring damper arrangement into the prototype 3 running shoe offered a reduction of the vertical loading rate within the first 5% of impact phase during forefoot impacts. Reductions of 34% and 19% respectively when compared against model 1 and model 2 of the commercial running shoes, see figure 5-20 below.

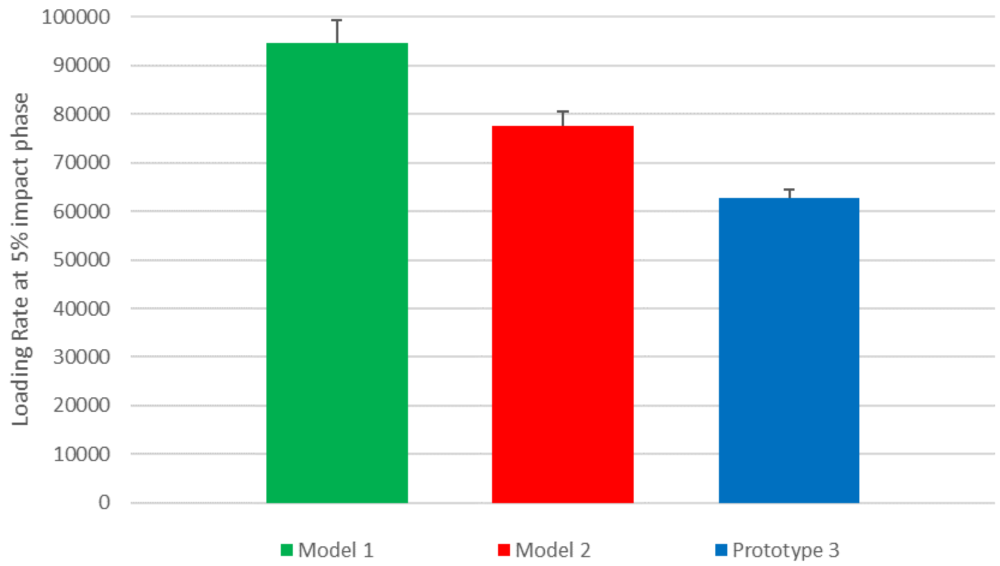

Figure 5-20: Forefoot initial vertical loading rate comparison at 5% of impact phase between prototype three and two models of popular branded running shoe

Significant differences were identified between all three test shoes as outlined in tables 5-6 and 5-7.

Table 5-6: Descriptive statistics of initial vertical loading rate results at 5% of impact phase for forefoot drop rig testing of third prototype

	Mean (SD)
Model 1	94707.27 (3550.17)
Model 2	77576.96 (3327.33)
Prototype 3	62682.48 (3244.97)

Table 5-7: Pairwise comparisons of initial vertical loading rate results at 5% of impact phase for forefoot drop rig testing of third prototype

Comparison		Mean Difference	p-Value	Confidence Interval of the difference (95%)
Model 1	**Model 2**	17130.30*	<0.001*	14031.89 to 20228.71
Model 1	**Prototype 3**	32024.78*	<0.001*	28926.37 to 35123.19
Model 2	**Prototype 3**	14894.48*	<0.001*	11796.07 to 17992.89

No reductions in initial vertical loading rate at 5% of impact phase were seen during rearfoot drop rig trials of the third prototype when compared against the popular branded running shoes. On this occasion, prototype 3 had the greatest mean loading rate value of all three shoes tested at the rearfoot, see table 5-8.

Table 5-8: Descriptive statistics of initial vertical loading rate results at 5% of impact phase for rearfoot drop rig testing of third prototype

	Mean (SD)
Model 1	61113.03 (2590.94)
Model 2	58623.73 (2987.42)
Prototype 3	63044.33 (1513.09)

At the analysis stage of this study, once it became clear that rearfoot performance of the prototype shoe was not in line with forefoot performance of the prototype shoe, the midsole depth of each test shoe was measured. Prototype 3 had a 21mm midsole depth at the rearfoot whilst model 1 of the popular branded running shoe had a midsole depth of 23mm and model 2 27mm. Significant differences in initial vertical loading rate at 5% impact phase were seen between model 1 and model 2, and model 2 and prototype 3 during rearfoot drop rig trials, see table 5-9.

Table 5-9: Pairwise comparisons of initial vertical loading rate results at 5% of impact phase for rearfoot drop rig testing of third prototype

Comparison		**Mean Difference**	**p-Value**	**Confidence Interval of the difference (95%)**
Model 1	**Model 2**	2489.30*	0.031*	246.19 to 4732.42
Model 1	**Prototype 3**	-1931.30	0.089	-4174.41 to 311.81
Model 2	**Prototype 3**	-4420.60	<0.001*	-6663.72 to -2177.49

Forefoot loading rate performance of prototype 3 had outperformed both popular branded running shoes tested against but the same could not be said of rearfoot performance where initial vertical loading rates within the first 5% of impact were significantly lower in model 2 compared to prototype 3.

Clear from the results was the repeatability of the drop rig testing methodology. Standard deviations reported in this study were typically less than 5% of mean values compared to the human running trials used when testing prototypes 1 and 2 which were typically between 20% and 30% of mean values due to the inter and intra subject variability of such methodology.

5.6.4 Discussion

The data from each shoe was remarkably repeatable, which allowed subtle but important differences between the brands and models to be identified during both rearfoot and forefoot impacts. It is vital that test rigs match as closely as possible the drop heights, peak forces and loading rates experienced with different running styles.

Differences between forefoot and rearfoot results indicate that the interaction between the EVA foam midsole and pocketed micro springs is critical for maximum spring damper performance. It was suggested this should lead to a closer examination of how the EVA foam midsole was interacting with the micro springs with respect to spring rate, micro spring to EVA foam ratio, and midsole depth.

Kulmala et al (2013) suggested forefoot strikers exhibit lower running induced loading than rearfoot strikers. They suggest runners using a forefoot strike pattern exhibit a different lower limb loading profile than runners who use rearfoot strike pattern, specifically in relation to the knee. This could offer one possible explanation as to why the pocketed micro spring technology appeared to perform better in forefoot impacts than rearfoot impacts, results demonstrated with respect to initial vertical loading rate at the rearfoot suggested there was scope to further enhance the final prototype.

5.6.5 Conclusions

It was concluded that repeatable testing is essential to determine the effects of different designs and materials and this cannot always be achieved with human testing. The results suggested that increasing the hardness of the EVA foam midsole had led to the development of a prototype that demonstrated reduced forefoot impact loading when compared against popular branded running shoes. This evaluation suggested partial fulfilment of one key objective of developing a technology capable of better reducing impact forces than technologies currently on the market.

5.7 High density pocketed micro spring technical modification

Work and modifications by the Harrison Spinks engineering team now enabled the micro spring production machine to run varied wire diameters. Throughout this process many technical challenges were presented including how to accommodate a wire feeding mechanism capable of dealing with a wire diameter increase. This development was achieved through technical alterations to the coiling points on the CNC machine and reprogramming of the indexing profile. It was also imperative that any alterations to the production machine did not slow down the pocketed micro spring output capabilities in order to retain the commercial viability of the technology. In order to further explore the effect of increasing the spring rate, a 1.4mm conical micro spring was created to replace the 1.3mm conical micro spring. It was hoped that this would lead to an improvement of rearfoot loading rate performance in the final prototype. The spring rate of the new 1.4mm conical micro spring was calculated as 5.505 N/mm.

5.8 Drop rig testing of final prototype

5.8.1 Introduction

The drop rig was again used to evaluate the loading profile of the final prototype which saw an increase in depth of the EVA foam midsole from 21mm (as it was in the third prototype) to 25mm. The increased depth also meant that a dual hardness EVA midsole could be introduced. This sat directly beneath the springs and was a combination of 45° and 55° on the Asker C Scale. Sterzing et al (2015) had previously found that non-uniform running shoe midsole density across the medio-lateral direction at the midfoot to forefoot may allow better negotiation of different loading magnitudes of the medial and lateral midfoot to forefoot during running. The 1.4mm pocketed micro spring technical development was also integrated for the final prototype. The final design can be seen in figure 5-21.

Figure 5-21: The final prototype

5.8.2 Methods

As with each of the previous studies, the final prototype was tested against the same two bestselling popular branded running shoes. Each shoe was mounted onto the drop rig and dropped directly onto a force platform 20 times on the forefoot and 20 times on the rearfoot. Prior to each drop trial, the 10mm drop height was checked and verified using a custom made measuring device. The differences in loading properties between the shoes were assessed using a one way ANOVA with post hoc pairwise comparison.

5.8.3 Results

The data from each shoe was remarkably repeatable, as seen previously with the drop rig testing on the third prototype, showing similar levels of consistency. This time similar impact properties were seen during rearfoot impacts between the final prototype shoe and the two market leading running shoes. No significant differences in initial vertical loading rate at 5% of impact phase during rearfoot trials were identified between the final prototype and model 1 and 2 of the popular branded running shoes, see figure 5-22 and table 5-10. As no significant differences were identified between groups a post hoc pairwise comparison was not run.

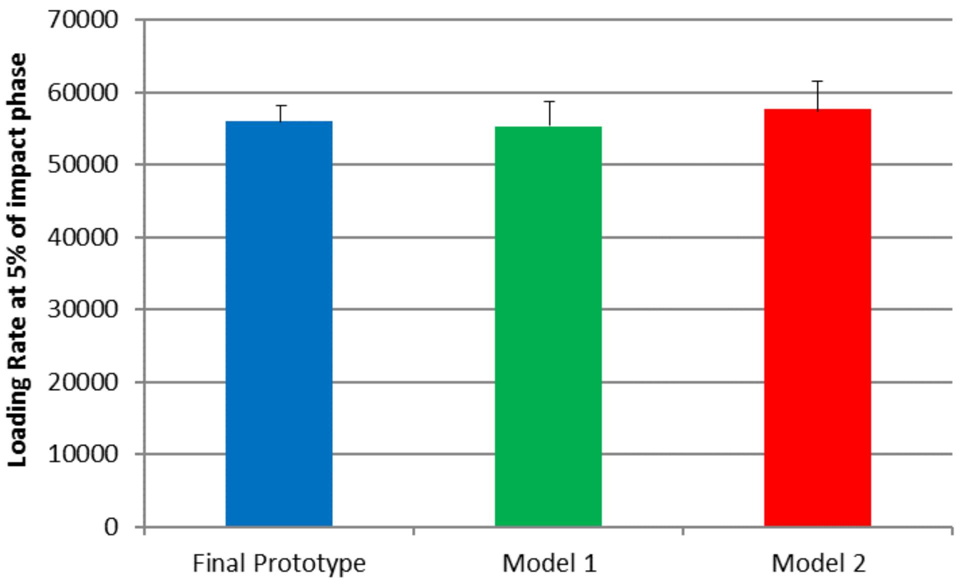

Figure 5-22: Rearfoot initial vertical loading rate comparison at 5% of impact phase between final prototype and two models of popular branded running shoe

Table 5-10: Descriptive statistics of initial vertical loading rate results at 5% of impact phase for rearfoot drop rig testing of final prototype

	Mean (SD)
Model 1	55285.48 (2247.81)
Model 2	57637.72 (4513.70)
Final Prototype	55941.68 (1957.93)

Results showed that the increase in the wire diameter, the increased midsole depth, and a dual hardness EVA foam in the final prototype running shoe offered a reduction of the initial vertical loading rates at 5% of impact phase of 8% and 32% respectively when compared against model 1 and model 2 of the branded market leading running shoes during forefoot impacts, see figure 5-23 below.

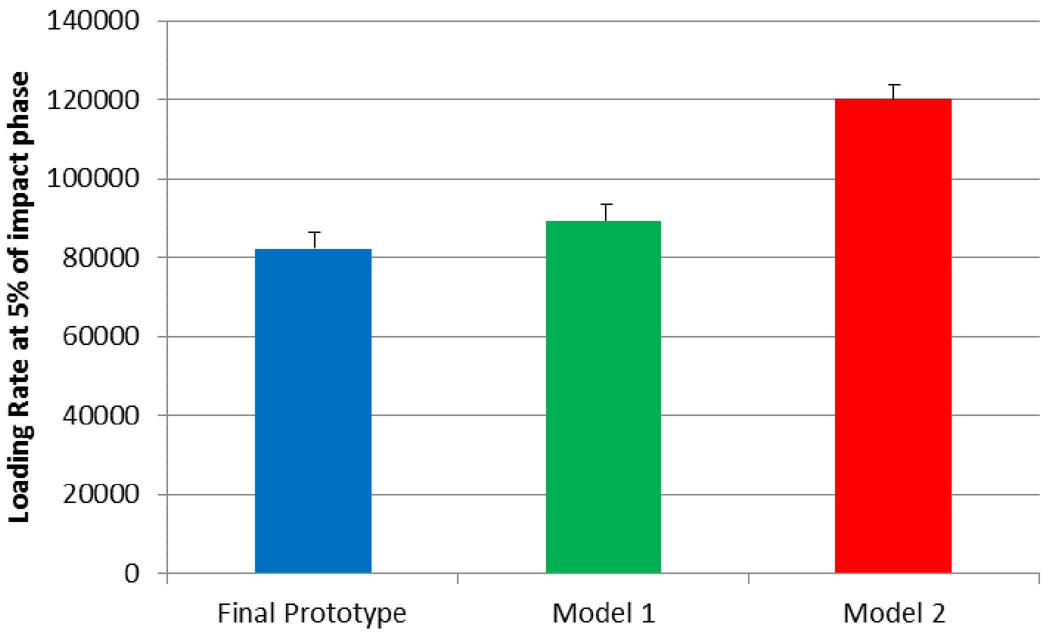

Figure 5-23: Forefoot initial vertical loading rate comparison at 5% of impact phase between final prototype and two models of popular branded running shoe

Significant differences in initial vertical loading rate at 5% of impact phase during forefoot trials were identified between the final prototype and model 1 and 2 of the popular branded running shoes, see tables 5-11 and 5-12.

Table 5-11: Descriptive statistics of initial vertical loading rate results at 5% of impact phase for forefoot drop rig testing of final prototype

	Mean (SD)
Model 1	89316.57 (4093.20)
Model 2	120227.05 (4008.05)
Final Prototype	82193.51 (3959.38)

Table 5-12: Pairwise comparisons of initial vertical loading rate results at 5% of impact phase for forefoot drop rig testing of final prototype

Comparison		Mean Difference	p-Value	Confidence Interval of the difference (95%)
Model 1	**Model 2**	-30910.48*	<0.001*	-35480.73 to -26340.23
Model 1	**Final Prototype**	7123.05*	0.001*	3391.46 to 10854.65
Model 2	**Final Prototype**	38033.54*	<0.001*	33463.28 to 42603.79

5.8.4 Discussion

Results suggested that the technical amendments made to the final prototype improved rearfoot loading rate performance when compared to the previous prototype, bringing it in line with both market leading running shoes. Although the forefoot loading rate performance was not quite at the level seen in the previous prototype, it was still significantly better than that in both market leading running shoes.

Drop rig testing not only provided a detailed exploration of performance differences between prototypes and possible market competitors, it also allowed an important gauge on the effect design and material changes had throughout the later stages of prototype development by providing a standardised method of assessment. The implications of introducing this device and methodology stretch beyond this project and could influence future research in this area.

5.8.5 Conclusions

After four prototype iterations, numerous design changes, and a wealth of scientific and technical testing, the final prototype sample was declared production ready. Intersport IC introduced a sample run of 10,000 pairs into retail stores across various countries in Europe, along with online and print marketing materials to support sales, see appendix G.

A commercially viable running shoe had been developed which integrated a mass-spring-damper system. The various studies in this chapter support the notion that high density pocketed micro spring technology is capable of reducing impact forces, specifically initial vertical loading rates, as well as, if not more effectively than, popular branded market leading running shoe technology. This point provided a clear watershed opportunity to move from a technical testing phase to explore the potential of pocketed micro spring technology to help runners currently suffering from injury, pain, or discomfort.

CHAPTER 6: EXPLORING THE BIOMECHANICAL PARAMETERS AND KNEE PAIN/COMFORT SCORES OF RUNNING IN DIFFERENT RUNNING SHOES

6.1 Introduction

The next phase of this research sought to explore the effect of pocketed micro spring technology on biomechanical factors commonly associated with runners suffering from knee pain or injury. The first stage of the research concluded with the successful development of an effective mass-spring-damper configuration capable of being integrated into a running shoe construction. The question of whether the mass-spring-damper configuration could have been further enhanced given more time is worthy of extended debate and is explored in more detail in Chapter 7. However, the result of the initial stage of the research was a complete and commercially available running shoe incorporating pocketed micro spring technology with rearfoot loading rates comparable to market leading running shoes and forefoot loading rates better than market leading running shoes. In essence, footwear with potentially clinically important shock absorption properties.

Figure 6-1: P1.0 running shoe on sale in Intersport store

Linking back to the original aims and objectives of the thesis (section 1.4), the aim of this study was to explore the effect of the pocketed micro spring technology on recreational runners currently suffering with knee pain. In order to do this, it was important to identify any potential biomechanical changes as a result of wearing running shoes integrating pocketed micro springs in injured runners as well as healthy runners, along with an assessment of subjective clinical measures (pain and comfort) when wearing the running shoes. From the work outlined in Chapter 5, specifically the development of a running shoe capable of reducing impact loading rates, and the current literature evidence associating reduced impact loading rates to lesser injury rates, it was hypothesised that training in the running shoes integrating the pocketed micro springs would improve the running experience of participants currently suffering from knee pain.

Recreational runners suffer from a wide variety of overuse related injuries, the aetiology of which have been explored extensively in the literature. The knee is one of the most common sites for running related injuries and discomfort (Taunton et al, 2002, Thijs et al, 2008). As detailed in the literature review, high loading rates are often associated with running related injuries (Zapdoor and Nikooyan 2011, Davies et al, 2010). Given the extensive focus given to loading rates in the first stage of this research through running trials in the movement analysis laboratory and drop rig testing, they were again investigated in the next phase of the research, along with other biomechanical parameters.

Key to this next stage of the research project was the evaluation of the micro spring technology in a more ecologically valid environment. Keen to test the running shoes in a real-life setting, all trials in the next stage of research took place outdoors on the surface most recreational runners predominately run, the pavement. This meant that loading rates could not be calculated from ground reaction force values recorded by the force platforms in the movement analysis laboratory as had been the case in stage one. For the outdoor trials accelerometers were used to record tibial accelerations. Some studies have demonstrated a strong correlation between loading rates and peak tibial accelerations (Lafortune, 1995, Greenhalgh et al. 2012). These acknowledge and summarise that bone acceleration measures may be adequate for the prediction of ground reaction forces and loading rates. Davis et al (2010) also used tibial shock differentiation to explore injury risk in recreational runners. A number of recent studies have used tibial acceleration measures to evaluate wearable technologies and footwear variants in relation to running and other sports including O'Leary et al. 2008, Bentley et al. 2015, and Sinclair et al. 2016.

Alongside tibial accelerations, analysis of the outdoor running trials would also include a measure of jerk. In engineering terms, jerk is the rate of change of acceleration, which is the derivative of acceleration with respect to time, and as such the second derivative of velocity, or third derivative of position. Jerk is a vector, the standard SI units of which are m/s^3. Given that loading rate is the rate of change of force, that is the derivative of force with respect to time, it was proposed as a biomechanical parameter equivalent to loading rate, see equation

6-1. Although jerk is not yet a term widely used in biomechanics, its intrinsic link to smoothness of movement in locomotion, and the link between excessive jerk and discomfort in engineering, made it a parameter worthy of investigation.

$$F = m\,a$$

$$F / t = \text{Loading Rate} = m\,a / t$$

$$\text{Jerk} = a / t \ (m/s^3)$$

Equation 6-1: Equations showing the link between Force, Loading Rate and Jerk

In addition to linear acceleration and jerk it is also possible to assess angular velocity using Inertial Measurement Units. These include a tri-axial gyroscope allowing measurement of angular velocity and internal rotation values. It has previously been suggested that certain knee injuries are caused by excessive internal tibial rotation (James and Jones, 1990; Tiberio, 1987) or a delayed external tibial rotation (McClay and Manal, 1997). Excessive internal rotation during the contact phase of running may delay the natural external rotation as the knee begins to extend. This has the potential to increase joint stresses at the knee and in turn cause injury (Bellchamber and van den Bogert 2000). Angular velocity, particularly with respect to eversion velocity and peak tibial internal rotation velocity, have also been explored as a potential risk factor for chronic injury development (Sinclair and Taylor, 2014). Accelerometers and gyroscopes have proven to provide accurate and reliable results in running gait measurement when the sensor used is triaxial and placed close to the area of interest (Norris, Anderson and Kenny, 2013).

Along with exploring biomechanical parameters linked to knee pain, it was also necessary to give thought to how runners felt the pocketed micro spring technology contributed to comfort rather than solely focusing on scientific factors. Any alteration in biomechanics may carry little relevance if the runner does not feel any reduction in knee pain. Likewise, any alteration in biomechanics may not be sustainable if the runner finds the footwear too uncomfortable to wear.

In this next stage of the research, each runner was asked to feedback on how comfortable the running shoes integrating the pocketed micro spring technology were to wear. Comfort is difficult to define however, it seems to be extremely important with respect to injuries and performance. In his book, Biomechanics of Sports Shoes (2010), Nigg is clear in his opinion that if one wants to develop a special cushioning product, comfort must be the central variable.

A number of studies have assessed comfort when evaluating movement related products such as orthoses, shoe insoles, sport shoes, surfaces and sport equipment. Mundermann et al (2003) explored the effects of construction material and shape of shoe inserts on comfort and concluded that comfort is an important indicator for the appropriate functioning of the lower extremities and for the reduction/prevention of locomotion related injuries. Twenty-one recreational runners volunteered for the study. Three orthotic conditions were compared with a control insert. Comfort for all orthotic conditions was assessed in each session using a visual analogue scale. The magnitude of differences in overall comfort varied between the three orthotic conditions. The control and the soft inserts were on average rated more than four comfort points higher than the hard insert. However, rather small, 0.56 comfort points, the difference in average overall ratings between the control insert and the soft insert. Interestingly all comparisons between orthotic conditions rated as significant regardless of large variability in the magnitude of actual differences.

Hagen et al (2010) made similar conclusions when investigating the effect of different shoe lacing patterns on running and perceived comfort. In this study fourteen experienced and symptom-free male rearfoot runners compared the shoe comfort and stability in the changed lacing conditions (right shoe) with the comfort and stability of the left foot, which was in the reference shoe (regular lacing) using an anchored 7-point perception scale (1= very very low, 7= very very high). They suggested that perceived comfort and stability could be related biomechanical measures during running trials.

Dinato et al (2015) published an interesting study investigating the perception of comfort and biomechanical parameters during running with four different types of cushioning technology in running shoes. Twenty-two men, recreational runners (18–45 years) ran 12 km/h with running shoes with four different cushioning systems. The results did not demonstrate significant relationships between the perception of comfort and the biomechanical parameters for the three out of four types of shoes investigated. Thus, they concluded, one cannot predict the perception of comfort of a running shoe through impact received. Despite this, significant differences were identified between the four conditions for both loading rate (p=0.025) and overall comfort (p=0.001). The actual difference between the condition with the highest and lowest loading rate was 4.9 N/ms and between the conditions with the highest and lowest comfort rating was 2.1 comfort points.

Based on his experimental and theoretical experiences over the last 40 years, Nigg concluded that comfort was probably the most important aspect of footwear and that it must be at the centre of any sports shoe development. Given that the current knowledge base for comfort as it relates to sports shoes is relatively small, yet there is a growing acknowledgement that it is an important field of knowledge, this research sought to investigate comfort as a key outcome measure. Links between biomechanics and comfort domains have also remained relatively elusive, this study aimed to explore this further.

6.2 Methods

This study aimed to recruit approximately 20 runners with knee pain and approximately 20 runners without knee pain. The inclusion criteria for the healthy group was that they must run at least 3 miles a week on a regular basis, be aged between 18 and 60 years old and not currently suffer from any injury or running related pain. The inclusion criteria for the knee pain group was that they must run at least 3 miles a week on a regular basis, be aged between 18 and 60 years old and currently suffer from some form of knee pain. Both male and female runners were encouraged to volunteer. Miles were used in the inclusion criteria rather than kilometres because the majority of the local running clubs asked recorded their training distances in miles.

Participants were recruited from a population of recreational runners which included attendees of local running clubs and members of the Harrison Spinks Ltd workforce. Participant recruitment was conducted by approaching the running clubs, with permission from the running club chairmen and by poster recruitment/via email on site at Harrison Spinks Ltd in Leeds, with permission from the managing director.

Each participant received a participation information sheet prior to the test session that provided information regarding what is involved in taking part in the study. Participants were then asked to complete a health screening questionnaire to ensure that the inclusion criteria were met, see appendix H. A consent form was also signed and witnessed prior to commencement of testing, see appendix B. All data recorded was anonymous and could not be traced back to any individual. All data and information recorded was coded and stored on password protected computers. A digital backup copy was also stored on the researcher's password protected computer.

The testing sessions took place at a designated facility at Harrison Spinks Ltd in Leeds, United Kingdom. This was an outdoor area, on flat land, and the running surface used was a pavement. Each participant was asked to wear typical running attire for the testing session, in all instances this consisted of some form of t-shirt and either shorts or running leggings. Prior to the trials information was gathered on shoe size, brand and model of current running footwear, length of time current running shoes had been owned, and average weekly mileage.

Data collection begun with each participant undertaking a 5 minute warm up activity in the test area, after which the accelerometer sensors were attached to both the left and right lower limbs on the skin over the anterior aspect of the distal tibia, see figure 6-2. The top of each sensor is shaped with an arrow to aid in the determination of orientation. In each instance, the arrow was placed pointing upwards, parallel to the tibia. The sensors were attached to the skin using a hypo-allergenic interface, manufactured from medical grade adhesive approved for dermatological applications. In addition, a flexifoam wrap was also wrapped around each tibia to secure the sensors. Measurements of distance from the anterior projection of both the medial and lateral malleolus to the sensor were taken to try best ensure sensor placement was the same for each participant and to give consistency for returning participants.

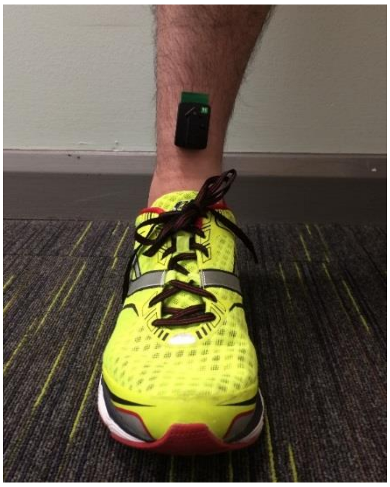

Figure 6-2: Inertial Measurement Units placement on test subjects

All participants were required to complete five running trials of approximately 80 metres in both the running shoe integrating pocketed micro spring technology and their regular running footwear. The order of which shoe was tested first was randomised and running speed was self-selected.

A total of 19 runners were successfully recruited for the healthy group. As this group did not suffer from any form of running related pain, only comfort scores were recorded. After completing the trials, each participant was asked to fill out the comfort questionnaire.

A total of 11 runners were successfully recruited for the knee pain group. Prior to the running trials, each knee pain participant was asked to complete the KOOS questionnaire to assess the runner's opinion about their knee problems. Immediately after completing the trials, each participant was asked to fill out the comfort questionnaire and the NPRS.

A Numeric Comfort Rating Scale (NCRS) evaluated the perception of comfort for both shoes evaluated in this research, the shoes integrating pocketed micro spring technology and the participant's regular running shoes. The NCRS was based on and adapted from a typical Numeric Pain Rating Scale (NPRS), more details are outlined in Chapter 4.6.3: Comfort. After trials, the runner rated three aspects of the shoe related to its comfort perceived. The comfort scale used a left anchor labelled 'not comfortable at all' (0 comfort points) and a right anchor 'most comfortable condition imaginable' (10 comfort points). Since many aspects of footwear may influence comfort, specific comfort ratings were included: forefoot cushioning, heel cushioning, and overall comfort. An example of the comfort questionnaire can be seen in appendix E.

In order to evaluate the effectiveness of pocketed micro spring technology to reduce knee pain the KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire was used. Selected because it is designed for individuals with different forms of knee conditions, rather than focusing solely on a specific type of knee pain, KOOS measures not only the general health of the knee, but also pain levels during sport and recreation activities, specifically running. Others researchers have used KOOS to assess the effect of interventions on knee pain in recreational athletes. Sinclair et al (2016) used KOOS to assess the influence of a knee brace intervention on perceived pain in recreational athletes.

KOOS is a popular choice in clinical trials and is widely used for research purposes. The reliability and validity of KOOS is explored in more detail in chapter 4.6.1. It can be used over long and short term intervals to assess week by week changes and the influence of an intervention. The questionnaire consists of five subscales; pain, other symptoms, function in daily living, function in sport and recreation and knee related quality of life. The previous week is the time period considered when answering the questions. Standardised answer options are given in the form of five likert boxes and each question is assigned a score from 0 to 4. A normalized score, 100 indicating no symptoms and 0 indicating extreme symptoms, is calculated for each subscale. The five individual KOOS subscale scores can be given as secondary outcomes to enable clinical interpretation. An example of the KOOS questionnaire can be seen in appendix C.

In addition to the KOOS questionnaire, a Numeric Pain Rating Scale (NPRS) was also used to evaluate levels of knee pain immediately post running trials in different footwear. This was to investigate the immediate response of the knee pain participants to the shoes with respect to pain scores, rather than only asking them to assess their pain over a longer 1 week period as with KOOS questionnaire. The NPRS is an 11-point scale from 0-10 with 0 representing “no pain” and 10 representing “worst possible pain”. The scale was set up on a horizontal line and was administered in written form, as with the comfort questionnaire. An example of the NPRS can be seen in appendix D.

Upon completion of the first testing session, members of the knee pain group were asked to take away the running shoes integrating pocketed micro spring technology and train in only this footwear for the next six weeks. No obligations were put in place with regards to frequency of use or mileage, each participant was asked to continue with their regular training regime.

Each member of the knee pain group scheduled to attend a second testing session approximately six weeks after the first testing session. The second testing session was a replication of the first with a warm up and completion of five running trials of approximately 80 metres in both the running shoe integrating pocketed micro spring technology and their regular running footwear, with acceleration, gyroscope, and jerk data recorded and a comfort questionnaire and NPRS completed immediately after.

Limitations in the number of test shoes available in each shoe size did serve to restrict the numbers recruited to the knee pain group. Of the 11 runners with knee pain that took part in the first testing session, 8 returned for the second testing session after six weeks of running in the shoes integrating the pocketed micro spring technology, 3 of the runners with knee pain dropped out of the study. Unfortunately, due to an equipment malfunction only 5 sets of biomechanical data from the knee pain group was available for analysis, all usable data from the knee pain group came from follow up trials in the second testing session.

6.3 Results: Healthy Group

6.3.1 Biomechanics

All results from the healthy subjects were grouped together and analysed as such using a general linear model two factor repeated measures ANOVA with post hoc pairwise comparisons in SPSS. The two factors were shoe condition and left/right side. The two shoe conditions explored were the running shoes integrating pocketed micro spring technology (P1.0's) and the subject's regular running shoes. Descriptive statistics including means and standard deviations were calculated for each condition with significance accepted at the ($p \leq 0.05$) level. An effect size measure was also included in the analysis (partial eta squared). The addition of the effect size allowed further analysis of how much of the independent variable was affected the dependent variable.

Each participant completed 5 running trials in each shoe condition. The average number of observed cycles per trial was 50. Approximately 250 cycles per shoe condition per side were collected, totalling approximately 1000 cycles per participant. As 19 runners were successfully recruited for the healthy group, the total data set for this analysis was approximately 20,000 cycles. Following on from the first stage of this research and the iterative prototype process, analysis focused on the initial 5% of stance in relation to each biomechanical variable explored. The first 5% following initial impact was identified after normalising the data to 101 data points using a linear interpolation technique.

In the grouped analysis, no significant differences were seen between left side and right side in any of the biomechanical parameters. Details of each parameter and the respective findings are outlined below.

The following two acceleration variables exhibited a significant response to wearing the pocketed micro spring technology in the healthy group, see table 6-1. The results showed significant differences between the two conditions for maximum anterior tibia acceleration (p= 0.019) and range of anterior/posterior tibia acceleration (p=0.013). The average percentage change in maximum anterior tibia acceleration (azmax) when wearing the P1.0s versus the subjects own running shoe was a 103.5% reduction, with an effect size of 0.268. The average percentage change in the range of anterior/posterior tibia acceleration (azrom) of wearing the P1.0s compared to the subjects own running shoes was a 24.7% reduction, with an effect size of 0.295.

Table 6-1: Repeated measures ANOVA and descriptive statistics of significant acceleration results for the healthy grouped analysis

	P1.0	**Own Shoe**	**Mean Difference**	**Confidence Interval of the difference (95%)**	**p - Value**	**Partial Eta Squared**
	Mean (SD)	**Mean (SD)**				
max ant tib acc	-0.033 (0.264)	0.954 (0.401)	0.987	1.796 to 0.179	0.019*	0.268
range ant/pos tib acc	4.457 (0.478)	5.920 (0.493)	1.463	0.344 to 2.582	0.013*	0.295

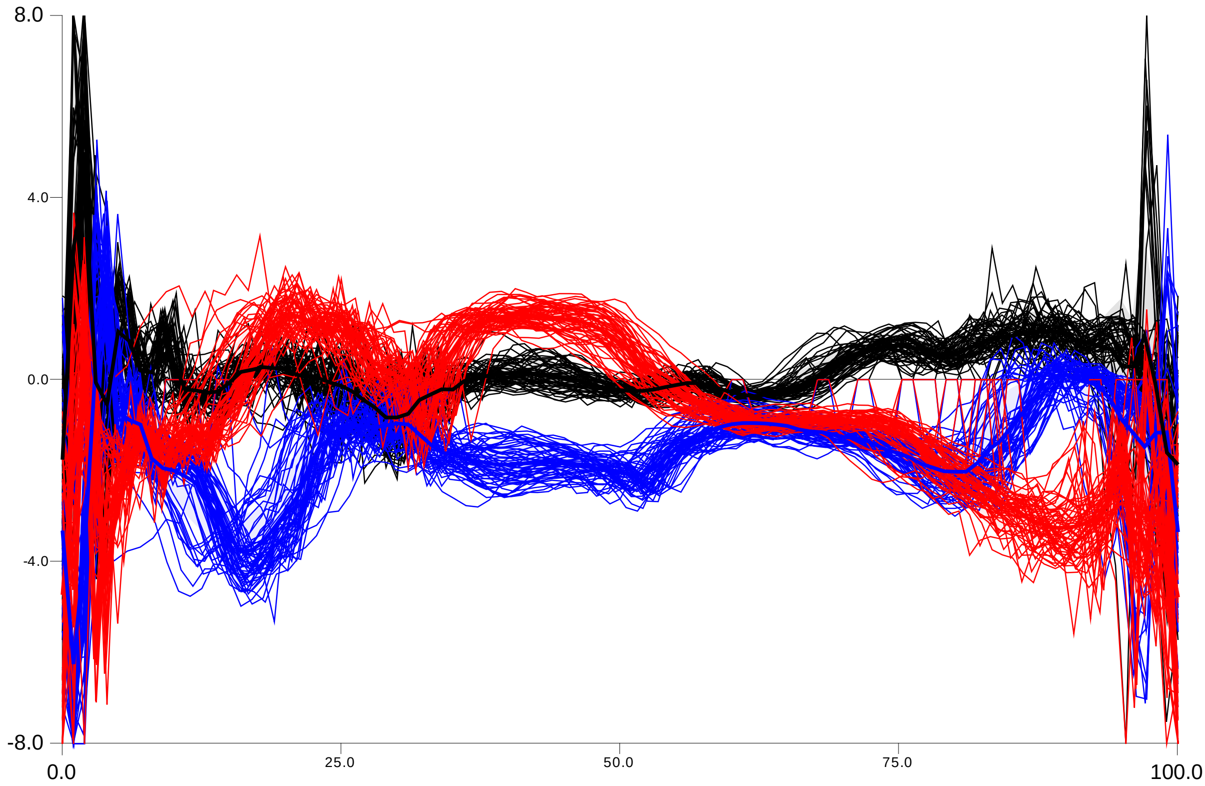

Figure 6-3: Example data from full acceleration profile in all three axes of one healthy participant wearing P1.0s, right side, all cycles.

The following four gyro variables exhibited a significant response to wearing the pocketed micro spring technology in the healthy group, see table 6-2. The results showed significant differences between the two conditions for flexion angular velocity of the tibia at impact (p=0.017), range of flexion/extension angular velocity of the tibia at impact (p=0.001), internal rotation angular velocity of the tibia (p=0.003) and range of internal/external rotation angular velocity of the tibia (p=0.007). The average percentage change in flexion angular velocity of the tibia (gxmin) when wearing the P1.0s compared to the subjects own running shoe was a 5.7% reduction, with an effect size of 0.276. The average percentage change in range of flexion/extension angular velocity of the tibia at impact (gxrom) when wearing the P1.0s compared to the subjects own running shoe was a 14.6% reduction, with an effect size of 0.482. The average percentage change in internal rotation angular velocity of the tibia at impact (gymin) when wearing the P1.0s compared to the subjects own running shoe was a 32.6% reduction, with an effect size of 0.399. The average percentage change in range of internal/external rotation angular velocity of the tibia at impact (gyrom) when wearing the

P1.0s versus the subjects own running shoe was a 25.5% reduction, with an effect size of 0.342.

Table 6-2: Repeated measures ANOVA and descriptive statistics of significant gyro results for the healthy grouped analysis

	P1.0	**Own Shoe**	**Mean Difference**	**Confidence Interval of the difference (95%)**	**p - Value**	**Partial Eta Squared**
	Mean (SD)	**Mean (SD)**				
flex ang vel	-493.579 (17.149)	-523.186 (18.494)	-29.607	-53.345 to -5.869	0.017*	0.276
range flex/ext ang vel	267.755 (17.892)	313.588 (18.352)	45.833	22.285 to 69.382	0.001*	0.482
int rot ang vel	-343.529 (61.071)	-509.508 (73.509)	-165.980	-266.751 to -65.208	0.003*	0.399
range int/ext rot ang vel	571.408 (88.100)	767.428 (100.772)	196.021	61.325 to 330.716	0.007*	0.342

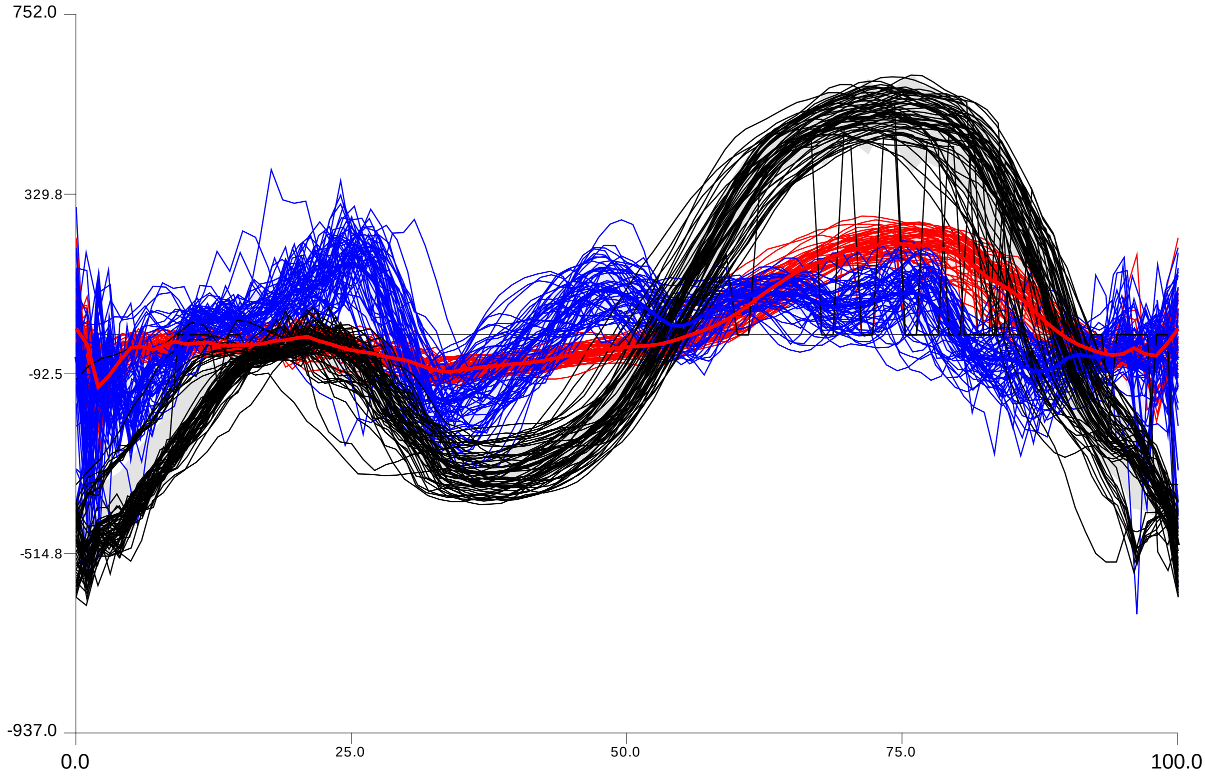

Figure 6-4: Example data from full gyro profile in all three axes of one healthy participant wearing P1.0s, right side, all cycles.

The following four jerk variables exhibited a significant response to wearing the pocketed micro spring technology in the healthy group, see table 6-3. The results showed significant differences between the two conditions for minimum vertical tibia jerk (p=0.019), minimum anterior tibia jerk (p=0.000), maximum anterior tibia jerk (p=0.047) and range of anterior/posterior tibia jerk (p=0.000). The average percentage change in minimum vertical tibia jerk (jymin) when wearing the P1.0s compared to the subjects own running shoe was an 11.7% reduction, with an effect size of 0.271. The average percentage change in range of minimum anterior tibia jerk (jzmin) when wearing the P1.0s compared to the subjects own running shoe was a 36.8% reduction, with an effect size of 0.548. The average percentage change in maximum anterior tibia jerk (jzmax) when wearing the P1.0s compared to the subjects own running shoe was a 15.3% reduction, with an effect size of 0.202. The average percentage change in range of anterior/posterior tibia jerk (jzrom) when wearing the P1.0s versus the subjects own running shoe was a 27.3% reduction, with an effect size of 0.505.

Table 6-3: Repeated measures ANOVA and descriptive statistics of significant jerk results for the healthy grouped analysis

	P1.0	Own Shoe	Mean Difference	Confidence Interval of the difference (95%)	p - Value	Partial Eta Squared
	Mean (SD)	Mean (SD)				
min ver tib jerk	-623.693 (51.927)	-706.353 (49.981)	-73.66	-133.521 to -13.799	0.019*	0.271
min ant tib jerk	-284.861 (28.273)	-450.497 (41.641)	-165.636	-240.148 to -91.124	0.000*	0.548
max ant tib jerk	306.733 (55.365)	363.159 (51.546)	56.426	0.911 to 111.940	0.047*	0.202
range ant/pos jerk	591.594 (74.042)	813.656 (70.913)	222.062	113.194 to 330.930	0.000*	0.505

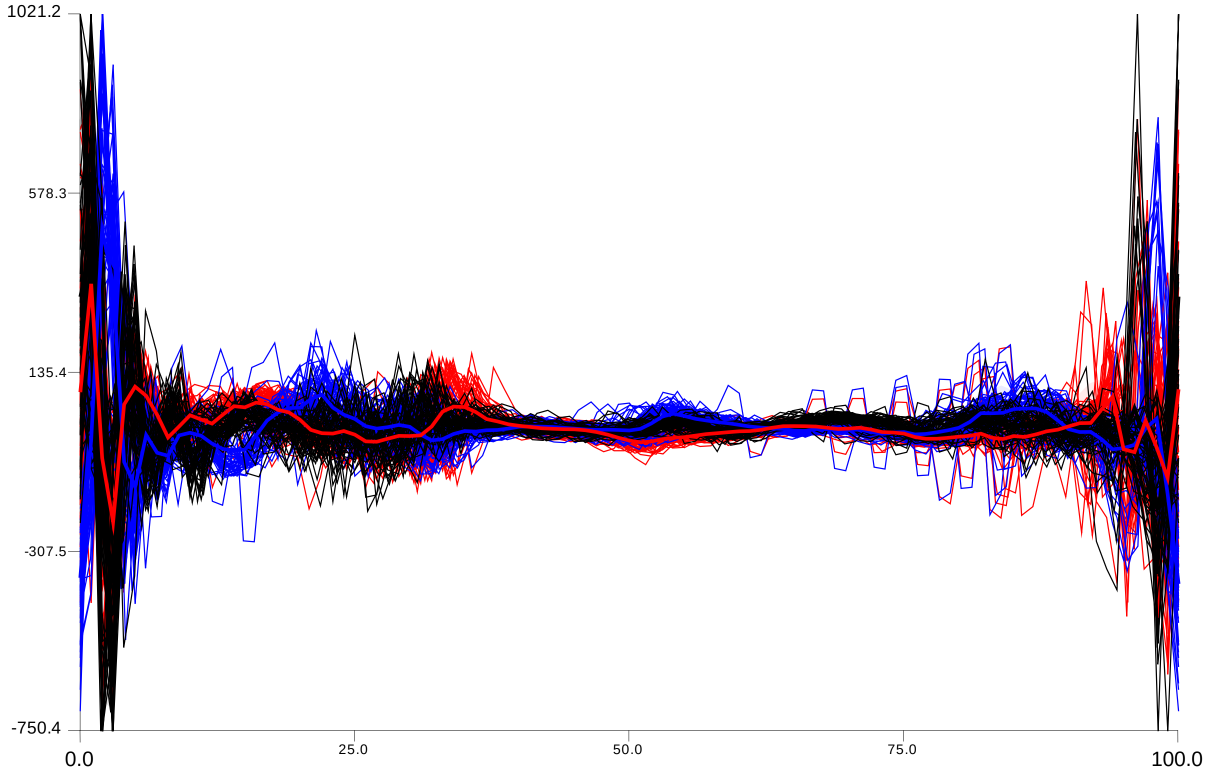

Figure 6-5: Example data from full jerk profile in all three axes of one healthy participant wearing P1.0s, right side, all cycles.

Table 6-4 provides a summary of the grouped analysis of the healthy group and their response to P1.0 running shoes integrating pocket spring technology during the running trials. Listed are each of the biomechanical parameters assessed (acceleration, angular velocity and jerk) in each plane of motion (x/y/z) and the minimum values, maximum values and range. Left and right side are also accounted for.

Table 6-4 uses a traffic light system to summarise and display the response between the measured variables and the response of the healthy group to the two conditions. The traffic light results demonstrate decreases (green), increases (red) and no change (amber) for the measured variables when wearing the P1.0 running shoes versus the subjects' own running shoes. The threshold used to represent an increase or decrease in each variable is consistent at 5%. Actual percentage change values are also listed for each biomechanical variable.

Significant results from the grouped analysis are indicated by (*) next to the variable name. Table 6-4 shows a trend towards reduced values across the majority of the biomechanical variables when wearing the pocketed micro spring technology in comparison to their regular running footwear.

Of the 27 biomechanical variables investigated 25 demonstrated reduced values on both the left and right side when wearing the pocketed micro spring technology in the healthy group. The only two variables which saw increased values when wearing the P1.0s were maximum gyro values in the x plane of motion (sagittal) and minimum gyro values in the z plane of motion (transverse). Out of the 27 biomechanical variables, 10 demonstrated a significant difference between the P1.0s and their own shoe in the grouped analysis.

Table 6-4: Results summary of biomechanical parameters – healthy group

		Right Side	Left Side
Acceleration	axmin	-3.4%	-15.0%
	axmax	-5.6%	-16.1%
	axrom	-4.6%	-15.8%
	aymin	-2.4%	-9.3%
	aymax	-9.5%	-12.7%
	ayrom	-3.8%	-10.1%
	azmin	-7.2%	-11.6%
	azmax*	-91.4%	-113%
	azrom*	-19.9%	-29.1%
Gyro	gxmin*	-3.7%	-7.5%
	gxmax	+6.5%	+4.5%
	gxrom*	-13.3%	-15.9%
	gymin*	-24.2%	-40.6%
	gymax	-12.1%	-11.3%
	gyrom*	-20.4%	-30.2%
	gzmin	+1037%	+104%
	gzmax	-1.1%	-15.9%
	gzrom	-10.4%	-21.4%
Jerk	jxmin	-12.2%	-23.8%
	jxmax	-8.9%	-18.7%
	jxrom	-10.2%	-20.6%
	jymin*	-6.9%	13.7%
	jymax	-1.0%	-6.7%
	jyrom	-3.9%	-10.1%
	jzmin*	-42.3%	-42.6%
	jzmax*	-4.6%	-25.1%
	jzrom*	-18.3%	-34.9%

In order to explore whether some subjects reacted differently to the pocketed micro spring technology, individual analysis was also conducted using Visual 3-D. For the individual analysis, the mean difference between the two conditions (pocketed micro spring running shoes and the subject's regular running shoes) were calculated for each subject for all 27 biomechanical variables, both left and right side. Again, a traffic light system was used to summarise the results. As it was with the grouped analysis, it can be seen from figure 6-6 that there is a trend towards reduced values across the biomechanical variables when wearing the pocketed micro spring technology in comparison to their regular running footwear.

Figure 6-6: Traffic light results for healthy subjects

The results highlight the fact that subjects responded in differing magnitudes to the conditions. Subjects in the healthy group did not show a uniform response to the pocketed micro spring technology. Inter-subject variability is evident within the data set with subjects employing different strategies and responses. Some subjects could be identified as non-responders, such as subject 7, 10 and 17, all of which exhibit more increased values than decreased values across the biomechanical variables assessed.

6.3.2 Comfort

Grouped analysis of the comfort ratings of the healthy group was achieved by averaging the data of all participants to provide mean comfort ratings for each subscale. Individual comfort rating scores were extracted, see appendix I, in order to appreciate the inter subject variability. Results showed a wide range of comfort ratings on the NCRS and thus demonstrated that the healthy group experienced variable levels of comfort throughout the trials. The average values were used to establish the percentage change in comfort ratings between the participants running in their regular running shoes versus running in the running shoes integrating pocketed micro spring technology (P1.0).

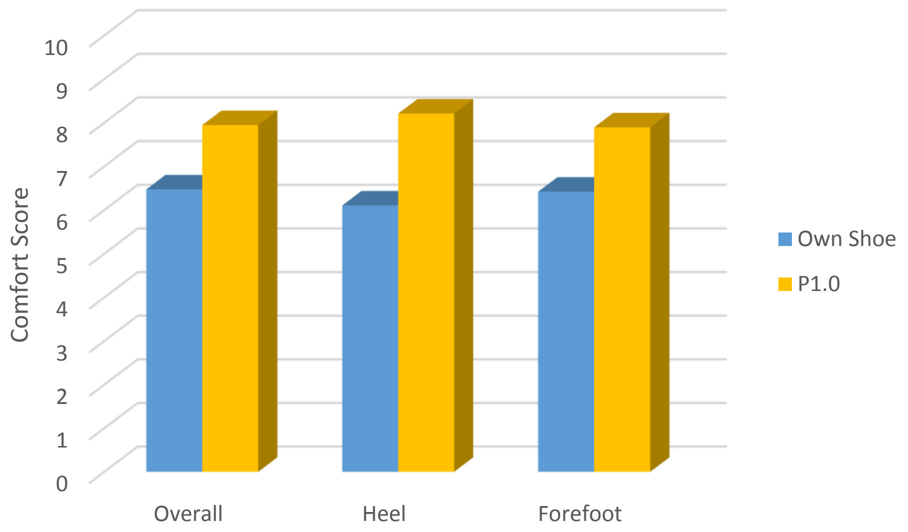

Figure 6-7: Mean comfort rating of all three subscales of the healthy group, regular running shoes vs P1.0

In the healthy group, for each of the three subscales, the mean comfort score was higher when wearing the running shoes with the pocketed micro spring technology than when wearing their regular running shoes. Overall comfort scores were found to be 22.8% higher in the P1.0s. Heel comfort scores were seen to be 34.5% higher in the P1.0s. Forefoot comfort scores were found to be 22.9% higher in the P1.0s. A paired sample t-test was conducted on the mean comfort scores of the participants when wearing their regular running shoes and the mean comfort scores of the participants when wearing the P1.0s. The results showed significant differences between the two conditions for each of the three subscales, overall (p=0.03), heel (p=0.00), forefoot (p=0.02).

6.4 Results: Knee Pain Group

6.4.1 Biomechanics

All results from the knee pain subjects were grouped together and analysed as such using a general linear model two factor repeated measures ANOVA with post hoc pairwise comparisons in SPSS. The two factors were shoe condition and left/right side. The two shoe conditions explored were the running shoes integrating pocketed micro spring technology (P1.0's) and the subject's regular running shoes. Descriptive statistics including means and standard deviations were calculated for each condition with significance accepted at the ($p \leq 0.05$) level. An effect size measure is also included in the analysis (partial eta squared).

Each participant completed 5 running trials in each shoe condition. The average number of observed cycles per trial was 50. Approximately 250 cycles per shoe condition was collected, totalling approximately 500 cycles per participant. 11 runners were successfully recruited for the knee group, unfortunately, due to an equipment malfunction only 5 sets of biomechanical data from the knee pain group was available for analysis, all usable data from the knee pain group came from follow up trials in the second testing session. The total data set for this analysis exceeded 2500 cycles. Following on from the first stage of this research and the iterative prototype process, analysis focused on the initial 5% of impact in relation to each biomechanical variable explored. The first 5% following impact was identified after normalising the data to 101 data points using a linear interpolation technique.

In the grouped analysis, no significant differences were seen between left side and right side in any of the biomechanical parameters. Details of each parameter and the respective findings are outlined below.

The following three gyro variables exhibited a significant response to wearing the pocketed micro spring technology in the knee pain group, see table 6-5. The results showed significant differences between the two conditions for internal rotation angular velocity of the tibia (p=0.022), external rotation angular velocity of the tibia (p=0.039) and range of internal/external rotation angular velocity of the tibia (p=0.030). The average percentage change in internal rotation angular velocity of the tibia at impact (gymin) when wearing the P1.0s compared to the subjects own running shoe was a 19.1% reduction, with an effect size of 0.768. The average percentage change in external rotation angular velocity of the tibia at impact (gymax) when wearing the P1.0s compared to the subjects own running shoe was a 30.0% reduction, with an effect size of 0.697. The average percentage change in range of internal/external rotation angular velocity of the tibia at impact (gyrom) when wearing the P1.0s compared to the subjects own running shoe was a 23.8% reduction, with an effect size of 0.723.

Table 6-5: Repeated measures ANOVA and descriptive statistics of significant gyro results for the knee pain grouped analysis

	P1.0	**Own Shoe**	**Mean Difference**	**Confidence Interval of the difference (95%)**	**p - Value**	**Partial Eta Squared**
	Mean (SD)	**Mean (SD)**				
int rot ang vel	-515.725 (136.553)	-637.277 (168.293)	-121.552	-214.394 to -28.709	0.022*	0.768
ext rot ang vel	337.107 (55.428)	481.494 (66.455)	144.387	12.331 to 276.443	0.039*	0.697
range int/ext rot ang vel	852.832 (156.471)	1118.770 (222.930)	265.939	42.771 to 489.107	0.030*	0.723

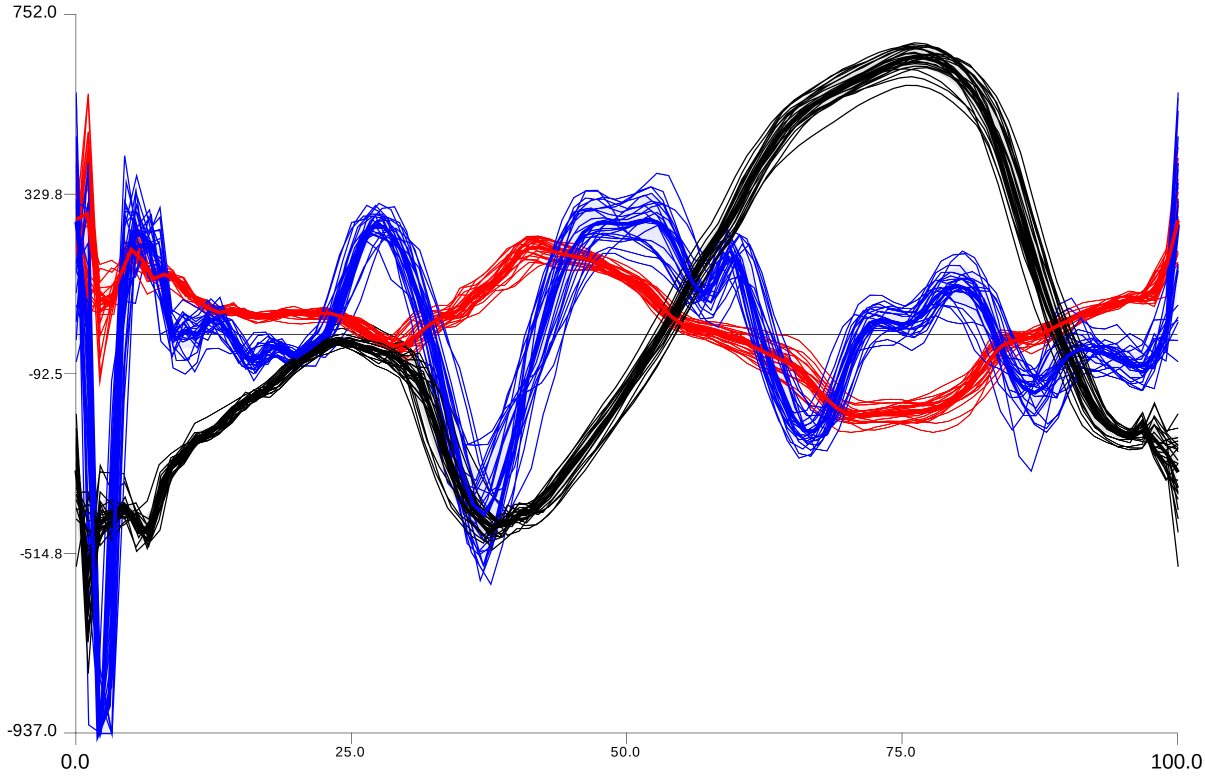

Figure 6-8: Example data from full gyro profile in all three axes of one knee pain participant wearing P1.0s, right side, all cycles.

The following jerk variable exhibited a significant response to wearing the pocketed micro spring technology in the knee pain group, see table 6-6. The results showed significant differences between the two conditions for maximum vertical tibia jerk (p=0.042). The average percentage change in maximum vertical tibia jerk (jymax) when wearing the P1.0s compared to the subjects own running shoe was a 16.0% reduction, with an effect size of 0.686.

Table 6-6: Repeated measures ANOVA and descriptive statistics of significant jerk results for the knee pain grouped analysis

	P1.0	Own Shoe	Mean Difference	Confidence Interval of the difference (95%)	p - Value	Partial Eta Squared
	Mean (SD)	Mean (SD)				
max ver tib jerk	505.237 (106.288)	601.699 (115.766)	96.462	5.786 to 187.139	0.042*	0.686

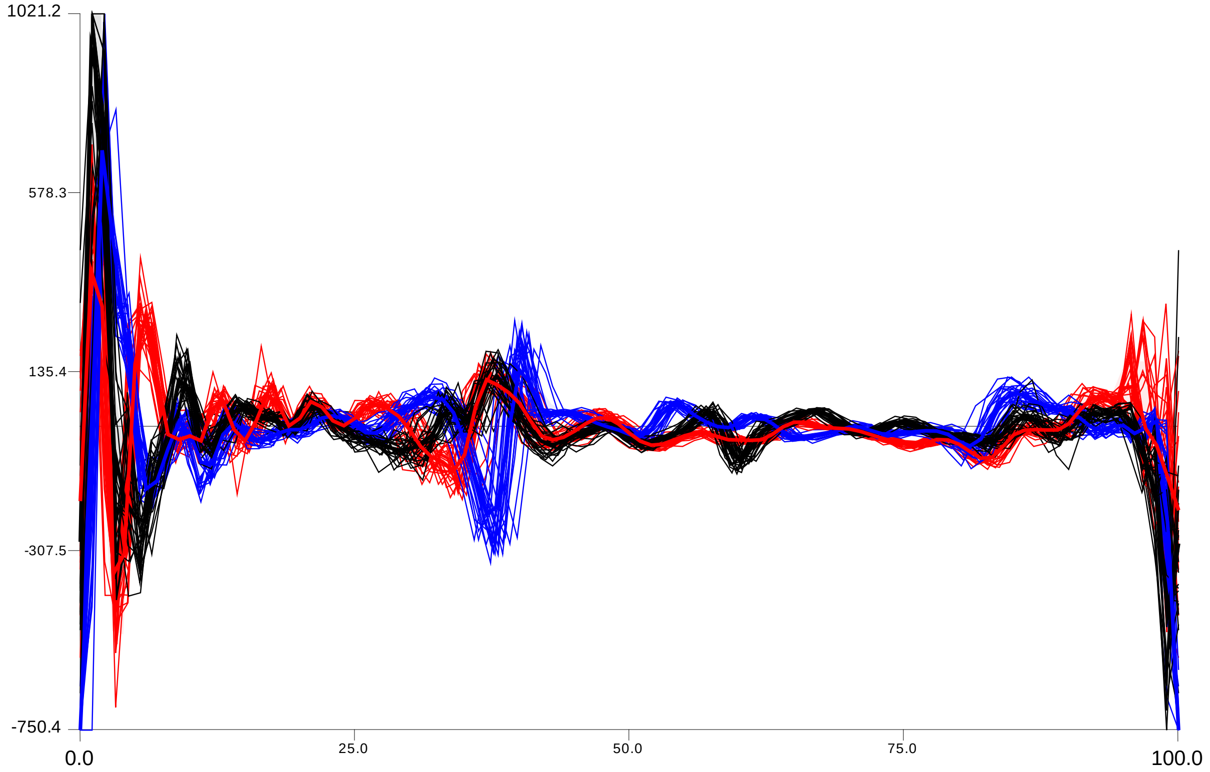

Figure 6-9: Example data from full jerk profile in all three axes of one knee pain participant wearing P1.0s, right side, all cycles.

Table 6-7 provides a summary of the grouped analysis of the knee pain group and their response to P1.0 running shoes integrating pocket spring technology during the running trials. Listed are each of the biomechanical parameters assessed (acceleration, angular velocity and jerk) in each plane of motion (x/y/z) and the minimum values, maximum values and range. Left and right side are also accounted for.

Table 6-7 uses a traffic light system to summarise and display the relationships between the measured variables and the response of the knee pain group to the two conditions. The traffic light results demonstrate decreases (green), increases (red) and no change (amber) for the measured variables when wearing the P1.0 running shoes versus the subjects' own running shoes. The threshold used to represent an increase or decrease in each variable is consistent at 5%. Actual percentage change values are also listed for each biomechanical variable.

Significant results from the grouped analysis are indicated by a * next to the variable name. Again, table 6-7 shows a trend towards reduced values across the majority of the biomechanical variables when wearing the pocketed micro spring technology in comparison to their regular running footwear.

Of the 27 biomechanical variables investigated, 17 out of 27 demonstrated reduced values on the right side, and 25 out of 27 demonstrated reduced values on the left side when wearing the pocketed micro spring technology in the knee pain group. Out of the 27 biomechanical variables, 4 demonstrated a significant response to the P1.0s in the grouped analysis, although no acceleration variables exhibited a significant response to wearing the pocketed micro spring technology in the knee pain group.

Table 6-7: Results summary of biomechanical parameters – knee pain group

		Right Side	Left Side
Acceleration	axmin	-19.7%	-21.3%
	axmax	-21.3%	-20.6%
	axrom	-20.4%	-21.0%
	aymin	+1.6%	-25.6%
	aymax	-25.5%	-30.5%
	ayrom	-1.2%	-22.0%
	azmin	-15.6%	-14.8%
	azmax	+642%	+6.0%
	azrom	+0.9%	-11.8%
Gyro	gxmin	-9.2%	-11.9%
	gxmax	-1.4%	-2.3%
	gxrom	-15.6%	-18.9%
	gymin*	-13.8%	-26.2%
	gymax*	-26.1%	-31.1%
	gyrom*	-16.5%	-29.0%
	gzmin	+398%	-13.2%
	gzmax	-20.5%	+67.2%
	gzrom	-27.4%	-24.9%
Jerk	jxmin	-29.4%	-25.7%
	jxmax	-28.1%	-16.8%
	jxrom	-28.5%	-22.4%
	jymin	+3.7%	-26.0%
	jymax*	+6.3%	-27.2%
	jyrom	+4.7%	-26.7%
	jzmin	+31.0%	-1.7%
	jzmax	+9.1%	-11.3%
	jzrom	+18.2%	-6.6%

In order to explore whether some subjects reacted differently to the pocketed micro spring technology, individual analysis was also conducted using Visual 3-D. For the individual analysis, the mean difference between the two conditions (pocketed micro spring running shoes and the subject's regular running shoes) were calculated for each subject for all 27 biomechanical variables, both left and right side. Again, a traffic light system was used to summarise the results. As it was with the grouped analysis, it can be seen from figure 6-10 that there is definitely a trend towards reduced values across the biomechanical variables when wearing the pocketed micro spring technology in comparison to their regular running footwear.

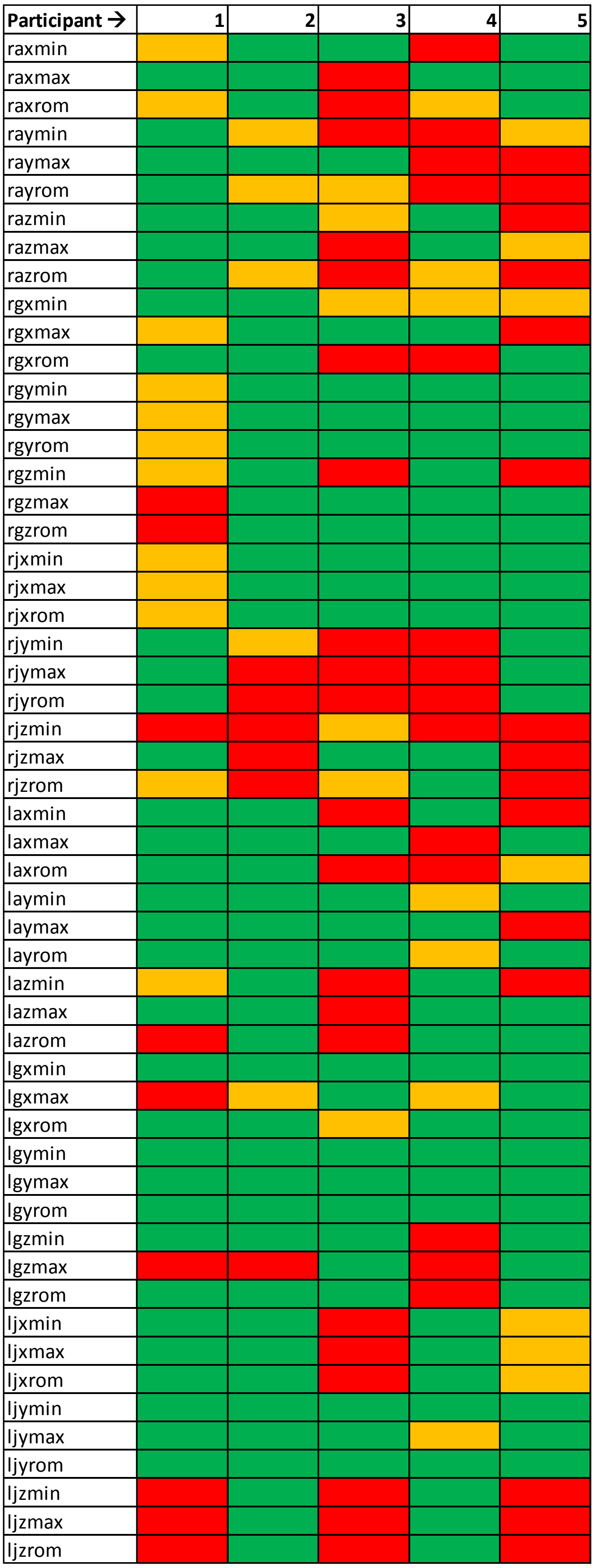

Figure 6-10: Traffic light results for knee pain subjects

The results highlight the fact that subjects responded in differing magnitudes to the conditions. Subjects in the knee pain group did not show a uniform response to the pocketed micro spring technology. Inter-subject variability is evident within the data set with subjects employing different strategies and responses.

All biomechanical data from both groups was also subjected to a linear mixed model analysis, enabling an isolated comparison between the healthy and knee pain group regardless of footwear condition, regardless of left and right side. This allowed mean values obtained from the healthy trials to be compared with mean values from the knee pain trials to determine if any fundamental differences in the biomechanical parameters existed between the two groups.

Table 6-8: ANOVA and descriptive statistics of significant results for the linear mixed model analysis

	Healthy	**Knee Pain**	**Mean Difference**	**Confidence Interval of the difference (95%)**	**p - Value**
	Mean (SD)	**Mean (SD)**			
min med tib acc	-4.5365 (3.16055)	-6.2478 (4.16523)	-1.711	-3.402 -0.021	0.047*
max ver tib acc	2.5126 (1.89432)	1.2549 (1.50649)	1.258	0.348 to 2.167	0.007*
int rot ang vel	-356.0542 (288.06766)	-576.5008 (537.00229)	-220.447	-396.510 to -44.383	0.015*
range int/ext rot	669.4179 (440.36105)	985.8010 (651.77120)	316.383	71.535 to 561.231	0.012*
max ver tib jerk	725.3238 (297.33763)	553.4681 (371.19647)	171.856	15.338 to 328.374	0.032*

Five biomechanical parameters demonstrated a significant difference between the healthy and knee pain group, see table 6-8. The average percentage difference in minimum medial tibia acceleration (axmin) between the healthy subjects and knee pain subjects was 37.8%. The average percentage difference in maximum vertical tibia acceleration (aymax) between the healthy subjects and knee pain subjects was 50.1%. The average percentage difference in internal rotation angular velocity of the tibia at impact (gymin) between the healthy subjects and knee pain subjects was 61.9%. The average percentage difference in the range of internal/external rotation angular velocity of the tibia at impact (gyrom) between the healthy subjects and knee pain subjects was 47.3%. The average percentage difference in maximum vertical tibia jerk (jymax) between the healthy subjects and knee pain subjects was 23.7%.

6.4.2 Comfort

Grouped analysis of the comfort ratings of the knee pain group was achieved by averaging the data of all participants to provide mean comfort ratings for each subscale. The knee pain group attended two testing sessions, the initial testing session was the first time the participants were given the opportunity to run in the P1.0s, the second testing session took place six weeks later after the participants had had chance to train in the P1.0s. Individual comfort rating scores were extracted, see appendix I, in order to appreciate the inter subject variability. Results showed a wide range of comfort ratings on the NCRS and thus demonstrated that the knee pain group also experienced variable levels of comfort throughout the trials. Again, the average values were used to establish the percentage change in comfort ratings between the participants running in their regular running shoes versus running in the running shoes integrating pocketed micro spring technology (P1.0).

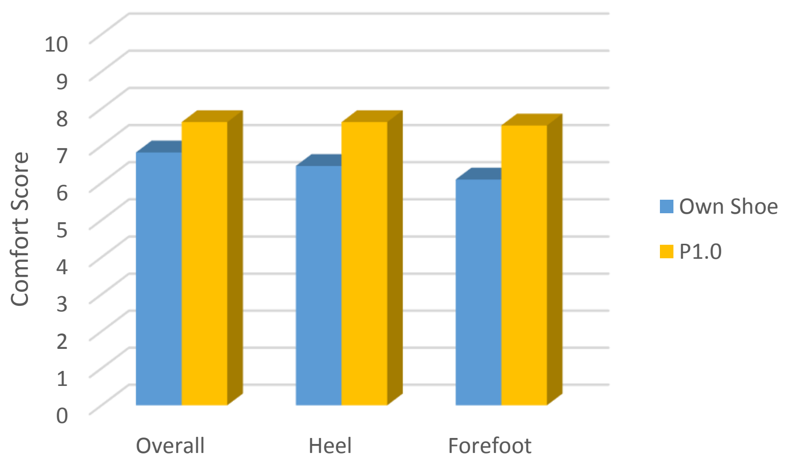

Figure 6-11: Mean comfort rating of all three subscales of the knee pain group, regular running shoes vs P1.0, initial testing session

In the knee pain group, as with the healthy group, for each of the three subscales, the mean comfort score was higher when wearing the running shoes with the pocketed micro spring technology than when wearing their regular running shoes in the first testing session. Overall comfort scores were found to be 12% higher in the P1.0s. Heel comfort scores were seen to be 18.3% higher in the P1.0s. Forefoot comfort scores were found to be 23.9% higher in the P1.0s. A paired sample t-test was conducted on the mean comfort scores of the participants when wearing their regular running shoes and the mean comfort scores of the participants when wearing the P1.0s. In this case, the results showed no significant differences between the two conditions for each of the three subscales, overall (p=0.19), heel (p=0.05), forefoot (p=0.07).

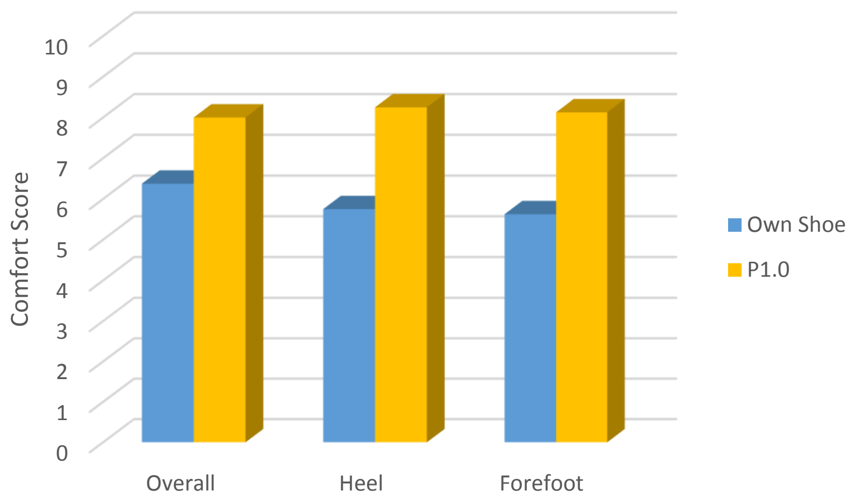

Figure 6-12: Mean comfort rating of all three subscales of the knee pain group, regular running shoes vs P1.0, second testing session

In the knee pain group's second testing session, after 6 weeks of training in the P1.0s, for each of the three subscales, the mean comfort score was again higher when wearing the running shoes with the pocketed micro spring technology than when wearing their regular running shoes. Overall comfort scores were found to be 25.5% higher in the P1.0s. Heel comfort scores were seen to be 43.5% higher in the P1.0s. Forefoot comfort scores were found to be 44.4% higher in the P1.0s. A paired sample t-test was conducted on the mean comfort scores of the participants when wearing their regular running shoes and the mean comfort scores of the participants when wearing the P1.0s. The results showed significant differences between the two conditions for two out of the three subscales, overall (p=0.10), heel (p=0.03), forefoot (p=0.03).

The mean comfort scores of the participants when wearing the P1.0s in the first testing session and the mean comfort scores of the participants when wearing the P1.0s in the second testing session were compared in order to understand whether levels of comfort increased over time when wearing the running shoes with the pocketed micro spring technology.

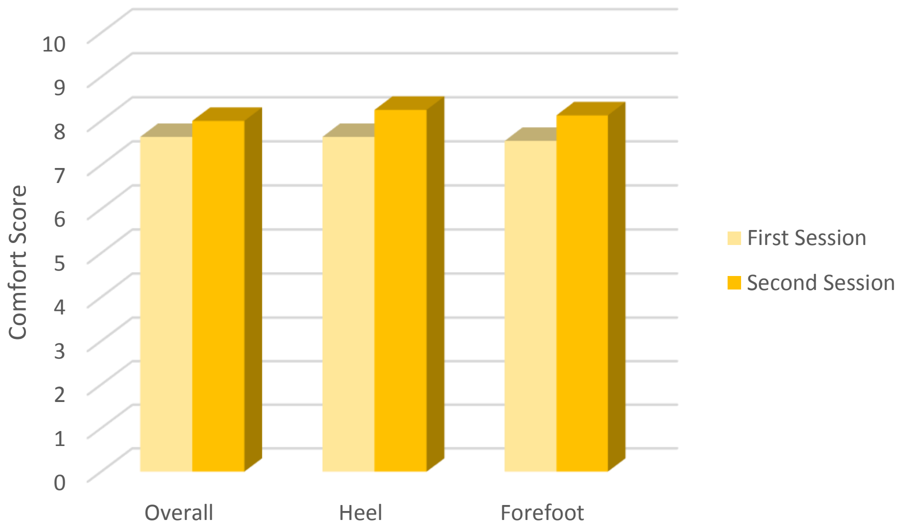

Figure 6-13: Mean comfort rating of all three subscales of the knee pain group, when wearing the P1.0s in the first testing session vs the second testing session

The mean comfort scores were higher when wearing the P1.0s in the second testing session compared to the first testing session. After 6 weeks of training in the P1.0s, overall comfort scores were found to be 4.8% higher in the second test session. Heel comfort scores were seen to be 8.0% higher and forefoot comfort scores were found to be 7.7% higher in the second test session. A paired sample t-test was conducted on the mean comfort scores of each of the three subscales, the results showed no significant differences.

6.4.3 Pain

The KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire was used in order to evaluate the effectiveness of pocketed micro spring technology to reduce knee pain. Each subscale score was calculated independently by calculating the mean score of the individual items of each subscale and dividing by 4 (the highest possible score for a single answer option). Traditionally 100 indicates no pain and 0 indicates extreme pain. Analysis of the KOOS scores of the knee pain group was achieved by averaging the data of all participants to provide mean KOOS scores for each subscale, both pre and post intervention. Individual KOOS rating scores were extracted, see appendix K, in order to appreciate the inter subject variability. To visualize differences in the five different KOOS sub scores and change between pre-intervention and post-intervention the KOOS profiles have been plotted on the graph below.

Figure 6-14: KOOS profiles pre and post pocketed micro spring technology running shoe intervention, mean KOOS scores

For each subscale the mean KOOS score post pocketed micro spring technology running shoe intervention was higher than the mean KOOS score pre-intervention, indicating a reduction in the levels of knee pain. For the pain subscale there was a 14.7% increase in the mean KOOS score. For the symptom and activities of daily living subscales, a 12.0% and 8.0% increase respectively. For the sport and recreation subscale there was a 29.3% increase in the mean KOOS score and in the quality of life subscale a 26.3% increase. A paired sample t-test was conducted on the mean KOOS scores of the participants pre-intervention and post-intervention. Of the 5 subscales, 3 showed significant differences between pre and post intervention, pain (p=0.01), sport and recreation (p=0.04), and quality of life (p=0.02).

Grouped analysis of knee pain group with respect to NPRS scores was achieved by averaging the data of all participants to provide mean pain ratings for each shoe. As the knee pain group attended two testing sessions, scores for pre and post pocketed micro spring technology running shoe intervention were analysed. Individual NPRS scores were extracted, see appendix J, in order to appreciate the inter subject variability. Results showed a wide range of NPRS scores and thus demonstrated that the knee pain group experienced variable levels of pain throughout the trails. The average values were used to establish the percentage change in pain ratings between the participants running in their regular running shoes versus running in the running shoes integrating pocketed micro spring technology (P1.0) both pre and post intervention.

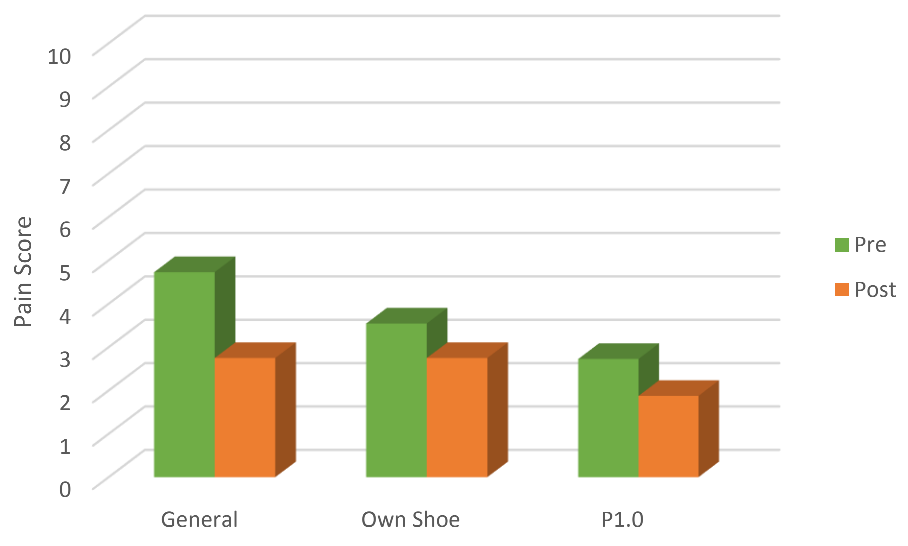

Figure 6-15: Mean NPRS scores of the knee pain group pre and post intervention

The mean NPRS scores were lower post pocketed micro spring technology running shoe intervention, in the second testing session, when wearing both the participants regular running shoes and the P1.0s, and in general. General pain ratings were seen to be 41.8% lower post intervention. Mean NPRS scores in the second test session were lower both when the participant was wearing their regular running shoes and the P1.0s, by 22.4% and 31.3% respectively. A paired sample t-test was conducted on the mean NPRS scores of the participants pre and post intervention. The results showed a significant difference in the general pain rating score between the first and second testing session (p=0.03).

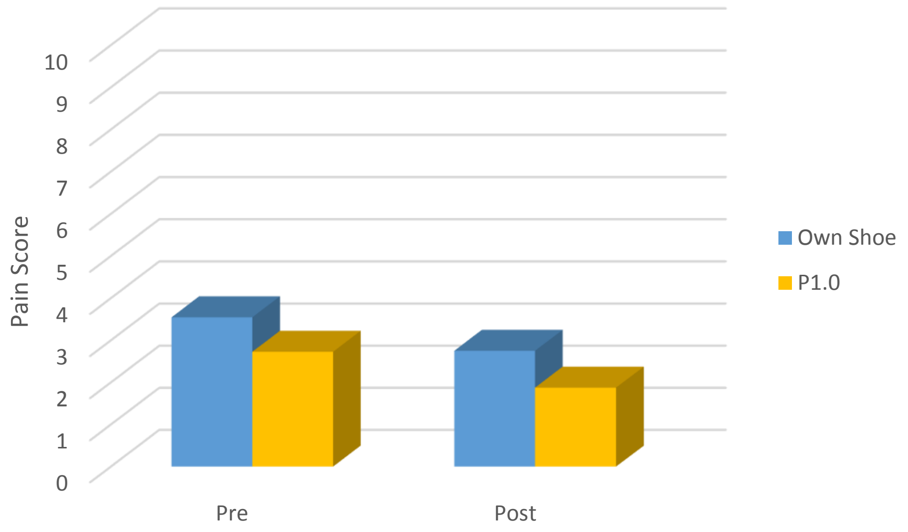

Figure 6-16: Comparison of mean NPRS scores of participant's when wearing their regular running shoes versus P1.0s both pre and post intervention

In both the first and second testing sessions, mean NPRS scores were lower in the P1.0s than the participants' regular running shoes. Pre-intervention, the mean NPRS score of the trials with the P1.0s was 23.1% lower than the mean NPRS score of the trials with the participants regular running shoes. Post intervention, the mean NPRS score of the trials with the P1.0s was 31.8% lower than the mean NPRS score of the trials with the participants regular running shoes. A paired sample t-test was conducted on the mean NPRS scores of each of conditions, the results showed no significant differences.

6.5 Discussion

6.5.1 Biomechanical measures

As mean values of both the healthy group and knee pain group demonstrated a trend toward decreased values for most biomechanical parameters, it can be concluded that the running shoe integrating pocketed micro spring technology contributed to altering the running biomechanics subjects usually exhibit when wearing their regular running shoes. This in itself is not unusual or surprising. A number of other studies have shown that running in different footwear will often lead to biomechanical changes. Strang et al (2016) suggested that recreational runners exhibited different lower extremity biomechanics when running in a maximal running shoe versus a traditional neutral running shoe. Similarly, Sterzing et al (2015) found that segmented differing midsole hardness in the midfoot to forefoot region of running shoes altered biomechanics during heel-toe running. In this case, maximum loading rate was significantly higher for shoes having softer medial hardness. Also, Goss et al (2015) investigated lower extremity biomechanics among runners in traditional and minimalist shoes. They found that minimalist shoe rearfoot strikers demonstrated a greater average vertical loading rate than traditional shoe rearfoot strikers.

In order to evaluate how the biomechanical changes seen in this study may contribute to possible reductions in knee pain and running injury/discomfort, it is necessary to explore the functional anatomy implications and discuss what the effect may be on internal structures.

6.5.1.1 Knee pain group

Focusing initially on the knee pain group, three tibial angular velocity variables exhibited a significant response to wearing the pocketed micro spring technology. The results showed significant differences between the two conditions for internal rotation angular velocity of the tibia, external rotation angular velocity of the tibia and range of internal/external rotation angular velocity of the tibia. It has been suggested that certain knee injuries are caused by excessive internal tibial rotation (Clement et al, 1981). During the stance phase of running, the tibia moves from internal rotation to external rotation during knee extension. The speed at which these movements happen has the potential to increase torsional joint stresses at the knee and in turn cause injury. Experimental work has verified coupling between the internal rotation of the tibia and the eversion of the foot (Nigg et al, 1993). As tibial rotation is linked to knee injuries and is coupled to eversion of the foot, this may imply that by controlling the speed of eversion with pocketed micro spring technology, this could reduce internal rotational velocity of the tibia and thus knee pain. One counter argument to this would be, if tibial rotation originates proximal to the tibia, and the foot merely follows the tibia, controlling eversion may increase the resistance against tibial rotation and cause more stress on the tibia and knee (Bellchamber and Bogert, 2000).

Mirzaie et al (2014) identified the rate of rotation of the tibia and the measured degrees of varus rotation of the tibia during running and other sports activities as a key risk factor for knee alignment associated injuries. This was based on a study focusing specifically on anterior cruciate ligament injuries in a group of 60 runners. Yeow et al (2010) also suggested reducing anterior tibial translation and axial tibial rotation could offer beneficial effects to the knee joint in their study looking at the effect of an anterior-sloped brace joint on knee injuries.

The average percentage changes in rotation angular velocity of the tibia at impact when wearing the P1.0s compared to the subjects own running shoe were 19.1%, 30.0% and 23.8% respectively for the internal, external and range. All demonstrated an effect size greater than 0.69. Estimates of effect size allow the assessment of the strength of the relationship between the investigated variables. In practice, they permit an evaluation of the magnitude and importance of the result obtained (Tomczak and Tomczak, 2014). These results suggest that micro spring technology had a significant effect on reducing internal rotation angular velocity of the tibia at impact.

Other studies support the notion that reducing angular velocity of the tibia at impact could lead to injury reduction. Sinclair et al (2013) compared tibiocalcaneal kinematics in barefoot inspired shoes and conventional running footwear. The results showed a significant main effect existed for the magnitude of peak tibial internal rotation velocity. Post hoc analysis revealed that the barefoot inspired shoe condition was associated with significantly greater peak tibial internal rotation velocity in comparison to the conventional running shoes. They note that the observations of this investigation have potential clinical relevance as excessive tibial internal rotation are implicated in the aetiology of injury.

Miller et al (2008) reported that at the end of an exhaustive run, runners with iliotibial band syndrome (ITBS) demonstrated a greater rearfoot inversion angle at heel strike compared to controls, which they hypothesized contributed to a greater peak knee (tibial) internal rotation velocity and thus torsional strain to the iliotibial band. This finding is consistent with that of Ferber et al (2010) who found female recreational runners who had previously sustained ITBS exhibited significantly greater knee internal rotation angles and velocity, and greater rearfoot invertor moments compared to a control group during running.

One jerk variable exhibited a significant response to wearing the pocketed micro spring technology in the knee pain group. The average percentage change in maximum vertical tibia jerk when wearing the P1.0s compared to the subjects own running shoe was a 16.0% reduction, with an effect size of 0.686. In engineering terms, jerk is the rate of change of acceleration, which is the derivative of acceleration with respect to time, and as such the second derivative of velocity, or third derivative of position. Given that loading rate is the rate of change of force, that is the derivative of force with respect to time, jerk was used as a biomechanical parameter equivalent to loading rate in this study.

Jerk is not yet a term widely used in biomechanics, although a couple of recent studies have begun to use the reference. When investigating forefoot angles during initial contact during running, Monaghan et al (2014) used jerk, the third derivative of the vertical position data, to define forefoot contact. Fukaya et al (2013) also used angular jerk cost to objectively represent the smoothness of joint movement by calculating the time-dependent changes in acceleration during motion. Within their study they acknowledge that there are currently no reports focusing on smoothness using angular jerk cost measurements of the knee joint movement during the stance phase of gait.

One of the most commonly studied variables that is thought to be associated with the development of running injuries is vertical impact forces during heel-toe landing. Repetitive heel strikes are related to bone loading and tissue injury. Assessed together, the impact peak and loading rate give a measure of frequency and hence the fatigue load of the soft tissues (Hreljac, 2004). High loading (impact peak) applied at a high frequency (loading rate/jerk) can increase the potential for overuse injury.

In a prospective investigation into greater vertical impact loading in female runners with medically diagnosed injuries by Davies et al (2015) all impact-related variables were higher in those with medically diagnosed injuries compared with those who had never been injured (effect size 0.4-0.59). In addition, vertical average loading rate was lower in female runners classified as 'never injured' compared with those who had been injured and sought medical attention. Outlined in chapter 3.4 are various studies that have explored impact loading of the lower extremity and its link to injury. Researchers such as Zapdoor and Nikooyan (2011), Crowell and Davis (2011) and Milner et al (2006) have all found significantly greater instantaneous and average vertical loading rates in runners who had suffered injury. Results from this study concur with the notion that reducing loading rate/jerk can contribute to reducing pain when running.

However, not all researchers agree that vertical impact force peaks and vertical impact loading rate are associated to running injuries. Nigg et al (2015) found no conclusive evidence that vertical impact forces are associated with running injury. They argue that the major reason for the fact that the results are not conclusive is the small sample sizes used in the cited studies, noting that as the study participant sample size increased, the relative frequency of running injuries decreased. They also argue that if higher impact peaks or loading rates were associated with running injuries one would expect runners who run faster have more impact-related injuries. However, there is no study or even anecdotal evidence that this is the case. Nigg instead proposes that comfort seems more important for the understanding of injury aetiology.

6.5.1.2 Healthy group

When assessing the healthy group, four tibial angular velocity variables exhibited a significant response to wearing the pocketed micro spring technology. The results showed significant differences between the two conditions for flexion angular velocity of the tibia at impact (5.7% reduction), range of flexion/extension angular velocity of the tibia at impact (14.6% reduction), internal rotation angular velocity of the tibia (32.6% reduction) and range of internal/external rotation angular velocity of the tibia (25.5% reduction). The fact that again, as with the knee pain group, significant changes were seen with regards to internal rotation angular velocity, this suggests that the pocketed micro spring technology is having an effect on the reduction of variable.

Four jerk variables exhibited a significant response to wearing the pocketed micro spring technology in the healthy group. The results showed significant differences between the two conditions for minimum vertical tibia jerk, minimum anterior tibia jerk, maximum anterior tibia jerk and range of anterior tibia jerk. As above, the fact that again, as with the knee pain group, significant changes were seen with regards to vertical tibia jerk, this suggests that the pocketed micro spring technology is having a definite effect on the reduction of this variable.

The average percentage changes in anterior tibia jerk at impact when wearing the P1.0s compared to the subjects own running shoe were 36.8%, 15.3% and 27.3% respectively for the minimum, maximum and range in the healthy group. All demonstrated an effect size greater than 0.2. When discussing loading rates in relation to running injury, much of the literature focuses on vertical values rather than anterior/posterior or medio/lateral. Although smaller in magnitude, anterior–posterior ground reaction forces applied to the lower extremity during the loading phase of stance may also influence loading of the tibia. Previous studies have produced conflicting results (Milner et al 2006). Grimston et al (1991) found runners with a history of tibia stress fracture demonstrated increased peak braking force. Milner et al (2006) found only small net differences in anterior–posterior instantaneous (6%) and average (2%) loading rates during initial braking between injured and non-injured groups.

Despite this, findings from this study suggest that the pocketed micro spring technology is having a defined effect on reducing anterior tibia jerk in the healthy group. This poses the question as to why this effect was not mirrored in the knee pain group and is perhaps worthy of further investigation. Much of the research carried out on this parameter to date has used force plates to assess lower extremity loading rates as a whole rather than isolating the tibia and looking at this area specifically.

Two acceleration variables exhibited a significant response to wearing the pocketed micro spring technology in the healthy group. The results showed significant differences between the two conditions for maximum anterior tibia acceleration and range of anterior/posterior tibia acceleration. The average percentage changes in anterior tibia acceleration at impact when wearing the P1.0s compared to the subjects own running shoe were 103.5% and 24.7% respectively for maximum and range in the healthy group. Both with an effect size greater than 0.26. Again, the question as to why this effect was not mirrored in the knee pain group should be addressed. From the summary results table for the knee pain group it can be seen that each anterior tibia acceleration variable demonstrated a sizable percentage reduction (all above 19%) when wearing the P1.0s compared to the subjects own running shoe. It is likely that this did not reach levels of significance in the knee pain group due to the smaller sample size.

6.5.1.3 Between group comparisons

Grouped analysis of both groups also demonstrated a large degree of variation between healthy subjects and knee pain subjects, regardless of shoe condition. There are a number of possible explanations for this. An interesting approach is to question whether the variations seen in certain biomechanical parameters are a result of a subject carrying an injury or the potential cause of the injury. For example, do the injured group have higher vertical loading rates because they are injured or was it that those subjects had higher vertical loading rates before injury and therefore acted as a cause of the injury. A prospective long term study would be required to answer this question fully. It is also possible to argue the reverse of this hypothesis. Do the injured group have lower vertical and anterior tibial jerk values because they are compensating for their injury and as such consciously or subconsciously making alterations to their stride pattern and internal mechanisms to avoid a heavy landing.

Interestingly two of the biomechanical parameters that demonstrated a significant difference between the healthy and knee pain group in the linear mixed model analysis, were also two of the parameters in which significant differences were seen in both the healthy and knee pain group analyses. These were internal rotation angular velocity of the tibia at impact and maximum vertical tibia jerk, adding further weight to the argument that these areas are of particular interest when looking at injury prevention and reduction.

6.5.2 Comfort

The results suggest that wearing the pocketed micro spring technology improved levels of comfort when subjects compared the experience of running in P1.0s to running in their regular running shoes. Mundermann et al (2002) claimed that comfort is an important factor for footwear in recreational physical activities and that most people can quickly identify comfortable or non-comfortable footwear situations. Physical properties, design and construction of footwear have been shown to affect variables such as vertical impact force, rearfoot motion and lower limb alignment (Nigg et al 1998).

Both the healthy group and the knee pain group demonstrated significant comfort improvements during trials wearing the footwear integrating micro spring technology. Mean scores for the healthy group showed overall comfort scores were found to be 22.8% higher, heel comfort scores 34.5% higher, and forefoot comfort scores 22.9% higher in the P1.0s. Mean scores for the knee pain group showed overall comfort scores were found to be 25.5% higher, heel comfort scores were seen to be 43.5% higher, and forefoot comfort scores were found to be 44.4% higher in the P1.0s after training in the shoes for a six-week period.

Results also suggest that the shoes integrating the pocketed micro spring technology became more comfortable over time. This may be due to the fact that the knee pain group also demonstrated reduced levels of pain after training in the P1.0s for six weeks. In other words, a possible correlational relationship may exist between reduced levels of pain and increased levels of comfort. Yet, a study by Lane et al (2014) into plantar pressure and comfort in older people with forefoot pain found that plantar pressure increases and pain did not appear to have a significant effect on shoe comfort, suggesting pain and comfort can be experienced independent to one another. Alternatively, it may be the case that as with most type of footwear, perceived levels of comfort are thought to increase over time. Hong et al (2015) examined whether the shoe usage time influenced the comfort perception of badminton shoes and found that prolonged shoe usage time does play a role in improving footwear comfort perception.

As comfort improvements were seen in the healthy group as well as the knee pain group, the author proposes that pocketed micro spring technology has had a direct effect on increasing levels of comfort in runners. Support for this proposal is offered by Mills et al (2010) who reported that a combination of heel cushioning and support, forefoot cushioning, and arch cushioning explained 69% of the overall comfort rating given for a running shoe, with heel cushioning having the strongest correlation with overall perception of footwear comfort. Sterzing et al (2015) also found that midsole densities and constructions influence subjective comfort. Miller et al (2010) listed cushioning as one mechanical variable of high importance in an investigation into subjective comfort of athletic shoes.

There is wide recognition of the importance of footwear comfort, particularly in relation to running shoes. Regardless of what biomechanical improvements a specific shoe may offer, it is unlikely to be worn if the runner does not find it comfortable to wear. Integrating a mass-spring-damper mechanism into a running shoe appears to enhance comfort, this can only be viewed as a positive outcome in relation to promoting running as a recreational activity.

6.5.3 Pain

Perhaps the most important measure evaluated in this thesis is the potential of pocketed micro spring technology to reduce levels of pain. The KOOS questionnaire was used to assess whether wearing the P1.0s for a six-week period would help runners currently suffering from knee pain. For each subscale the mean KOOS score post pocketed micro spring technology running shoe intervention was higher than the mean KOOS score pre-intervention, indicating a reduction in the levels of knee pain. Three of the five subscales showed significant differences between pre and post intervention, with a 29.3% increase in the mean KOOS score for the sport and recreation subscale.

The Minimal Important Change (MIC) for the KOOS questionnaire is currently suggested to be 8-10 (Roos and Lohmander, 2003). However, the current understanding is that MIC is dependent on factors such as patient group, intervention and time to follow-up. Monticone et al (2013) suggested the minimal important changes for the sport and recreation subscale is 12.5. Mean scores from this study demonstrate a 15.7 increase on the sport and recreation subscale post pocketed micro spring technology intervention. All other subscales demonstrated a post intervention increase of between 7 and 15.

Sinclair (2016) used the KOOS questionnaire to explore the effects of a 10 week footstrike transition in habitual rearfoot runners with patellofemoral pain. Improvements were shown for all subscales post transition. Mean scores from this study demonstrated a 19.0 increase on the sport and recreational subscale (pre-transition = 53.6 and post-transition = 72.6). This linked to reductions found in peak patellofemoral force measurements post transition. Similarities exist between this study and that presented in this thesis with respect to reduced biomechanical variables and reduced pain scores. An interesting consideration would be to explore whether over the course of the 6 week training programme in the pocketed micro spring technology participants’ footstrike pattern altered at all.

An NPRS questionnaire was also used as another measure to assess whether wearing the P1.0s for a six-week period would help runners currently suffering from knee pain. In both the first and second testing sessions, mean NPRS scores were lower in the P1.0s than the participants' regular running shoes. Post intervention, the mean NPRS score of the trials with the P1.0s was 31.8% lower than the mean NPRS score of the trials with the participants regular running shoes. Abbott and Schmidt (2014) reported the minimum important difference (MID) for an NPRS to be between -1.5 and -3.5 (small change to large change). General levels of pain reduced by 2 points on the NPRS between the first and second testing sessions in this study.

Integrating a mass-spring-damper mechanism into a running shoe appears to reduce pain, again this can only be viewed as a positive outcome in relation to promoting running as a recreational activity. However, much has been reported on the pros and cons of self-reported pain measures. Some have suggested such measures have good evidence for reliability, content validity and construct validity, along with evidence for responsiveness (Garett et al 2004). They are also rank high on ease of administration and simplicity for scoring (Jensen et al, 1986) and sensitivity (Williamson & Hoggart, 2005). Yet, in studies such as this it can be difficult to establish whether it was specifically the micro spring technology intervention that influenced the reduction in pain levels, or whether any other intervention could have had the same effect.

6.5.4 Comparing biomechanics and clinical measures

From the results of this study it is evident that pocketed micro spring technology played a role in altering biomechanical parameters, increasing comfort and reducing pain. Worthy of further discussion is whether each of these outcomes are related and in some way linked, or, whether these findings are completely independent of one another. Put another way, do biomechanical changes directly affect clinical outcome scores and how can one measure the magnitude or direction of any causal relationship?

The relationship between the perception of comfort and biomechanical parameters during running has been investigated by a number of researchers. Dinato et al (2015) began an investigation into biomechanical variables and perception of comfort in running shoes with different cushioning technologies with the hypothesis that there would be significant correlations between rearfoot impacts and forefoot forces and the perception of comfort with cushioning technology running shoes. Instead they found no significant relationships and concluded that one cannot predict the perception of comfort of a running shoe through impact.

Nigg et al (2015) recently proposed the comfort filter paradigm. They suggest that when selecting a running shoe, an athlete selects a comfortable product using his/her own comfort filter. This automatically reduces the injury risk and may be a possible explanation for the fact that there does not seem to have been a trend in running injury frequencies over time. Again supporting the notion that comfort is not automatically related to biomechanical changes.

In contrast, Mundermann et al (2003) suggested 34.9% of differences in comfort were explained by changes in 15 kinematic, kinetic, and EMG variables and proposed future research should focus on defining the relationship between comfort and biomechanical variables for material modifications of footwear. Support for this theory also comes from studies into other sports, for example, when exploring the effect of boot insoles on comfort and loading during running in soccer, Nunns et al (2016) found that perceptions of comfort and biomechanical results highlight the need for a multi-faceted approach in the assessment of footwear.

The relationship between pain and biomechanical parameters during running has also been explored extensively but few have monitored pain reductions in line with biomechanical changes. Most studies to date have been retrospective in nature and focused on establishing the biomechanical differences between injured groups and control groups, largely categorising a pain group as those suffering from an injury. The majority of research to date concerning running injuries is limited as it has also classified pain as a unidimensional construct and simply recorded as a singular value in an attempt to quantify it and not explored the degree to which subjects are in pain, or how it has improved over time. In other words, an over simplification binary representation, pain is either present or it isn’t, and therefore the subject can either run or they cannot. In reality, pain is comprised of many more subtleties. Each subject in the knee pain group in this study suffered from knee pain but all were still actively running. Individual analysis of both KOOS scores and NPRS scores show a wide range of values and thus demonstrated that the knee pain group experienced variable levels of pain throughout the trials.

The International Classification of Functioning, Disability and Health (ICF) is a framework for describing and organising information on functioning and disability. It provides a standard language and a conceptual basis for the definition and measurement of health and disability. Using terminology from the ICF the knee pain group in this study represent a population that have a health condition but who are still able to participate in their chosen activity.

Frequently in research exploring injury the terms “pain” and “discomfort” are used interchangeably. Whilst it may be sensible to propose that those in pain are most likely suffering some form of discomfort, it may not be the case that those in discomfort would necessarily classify themselves as in pain. This topic of discussion is often brought up in the nursing profession in relation to verbal patient feedback. Should the response to pain and discomfort be different? Is the necessity of an intervention dependent upon which term is used? Chooi et al (2013) found that the same group of post-operative patients rated their pain and comfort scores very differently to one another suggesting patient perceptions differ between the two terms. With pain recognised as a major barrier to activity and comfort increasingly stressed as an important consideration when running by Nigg etc, both measures are worthy of assessed contribution in their own right.

Analysis of individual subjects’ results offer very few trends or patterns to establish a causal relationship between biomechanical changes, comfort and pain. Those who demonstrated the largest and most comprehensive reductions in biomechanical factors were not necessarily those who experienced the greatest reductions in pain or the largest improvements in comfort and vice versa. A good example of this would be looking at the results of subjects 7 and 8 of the healthy group specifically. Subject 8 demonstrated reductions in almost all biomechanical variables whilst subject 7 could be classed as a non-responder when taking into account purely biomechanical parameters. Yet, both subjects showed clear improvements in comfort ratings when wearing the running shoes integrating pocketed micro spring technology. However, general trends from group analysis show a very clear relationship to suggest that the pocketed micro spring technology intervention was the common theme in significant reductions in key biomechanical parameters, significant increases in comfort levels and significant reductions in levels of knee pain amongst a population of recreational runners.

6.6 Conclusions

Analysis of both the healthy and knee pain groups demonstrated a trend towards decreased values of most biomechanical parameters when wearing the pocketed micro spring technology. Significant differences were seen across acceleration, angular velocity and jerk. Some parameters that were found to have significant reductions in the knee pain group were also found to have significant reductions in the healthy group as well, so an element of crossover was evident.

In the grouped analysis of both groups, no significant differences were seen between left and right sides in any of the biomechanical parameters. Individual analyses of subjects provided evidence of a non-uniform response to the pocket micro spring technology. Mean differences exhibited changes dependent upon subject, parameter and condition, with some values decreasing and others increasing. A large degree of variation was also seen between the healthy group and knee pain group regardless of shoe condition or left and right side, with some significant differences.

Analysis of both the healthy and knee pain groups demonstrated higher mean comfort scores for the condition wearing the pocketed micro spring technology than the subject's regular running shoes. This was evident across all three subscales (overall, forefoot and rearfoot) and results showed significant differences between the two conditions. Mean comfort scores were also higher when wearing the P1.0s in the second testing session compared to the first testing session, suggesting levels of comfort increased over time when wearing the running shoes with the pocketed micro spring technology.

The mean KOOS score post pocketed micro spring technology running shoe intervention was higher than the mean KOOS score pre-intervention, indicating a reduction in the levels of knee pain when the P1.0 running shoes are worn for a 6-week period. 3 the 5 subscales showed significant differences between pre and post intervention, including sport and recreation.

Analysis of knee pain group with respect to NPRS scores showed subjects experienced lower levels of pain when wearing the P1.0 running shoes compared to their regular running shoes. The results showed a significant difference in the general pain rating score between the first and second testing session, again suggesting during the 6 week training period in the pocketed micro spring running shoes, pain levels reduced.

It can therefore be concluded that pocketed micro spring technology had a significant effect on reducing biomechanical values linked to injury risk, improving levels of comfort and reducing reported pain measures in both a healthy population and a group of runners suffering from knee pain. The P1.0 running shoe and the mass-spring-damper system housed within it had proved effective in helping knee pain sufferers and improving their running experience.

CHAPTER 7: FINAL CONCLUSIONS AND RECOMMENDATIONS FOR FURTHER WORK

7.1 Summary

The main aims of this work were to identify whether pocketed micro spring technology could be viably and effectively integrated into a commercial branded running shoe and to explore the effect of the technology on recreational runners currently suffering with knee pain. The research conducted during this thesis identified that it was possible to develop a pocketed micro spring capable of reducing impact forces, specifically initial vertical loading rates, as well as, if not more effectively than, popular branded market leading running shoe technology, and create a commercially viable running shoe integrating a mass-spring-damper system. In human outdoor trials, wearing pocketed micro spring technology led to reductions in the majority of biomechanical parameters assessed for both healthy and knee pain populations. Internal rotation velocity of the tibia at impact and vertical jerk at impact in particular were identified as significant and clinically important variables. Recreational runners currently suffering with knee pain were recorded as feeling lower levels of pain and greater levels of comfort when wearing and training in pocketed micro spring technology. Although a clear correlation was evident between biomechanical changes, pain and comfort, no causal relationship was established.

Perhaps the most important requirement of this research was to establish a system better equipped to reduce the pain from which a number of recreational runners suffer. It can be concluded that pocketed micro spring technology does offer an improved solution to a knee pain sufferer's regular running shoes. The significance of any research should be contextualised with minimum important differences in mind where possible to justify the reliability of any observed change. As this work presents proven techniques but within a new and novel setting, it could be argued that MID's are open to debate. However, as significant differences were framed within a percentage change, and the study design combines biomechanical and clinical measures, a high degree of confidence can be taken in the conclusions offered.

This work, in addition to the main findings, offered various contributions and insights to the understanding of the existing literature in this area. Namely, the findings of this thesis support current suggestions that impact loading rates and tibial rotation are risk factors associated with knee pain in runners. This work approached knee pain with an inter-disciplinary approach by simultaneously investigating biomechanical and clinical measures, and their response to an intervention using advanced technologies. The study also presented a novel method of exploring impact loading through jerk. Although jerk is not yet a term widely used in biomechanics, its intrinsic link to smoothness of movement in locomotion, and the link between excessive jerk and discomfort in engineering, made it a parameter worthy of investigation. Furthermore, a new drop rig testing machine was developed that can replicate both rearfoot and forefoot impact loading during running to determine the effects of subtle differences in the design and materials used in running shoes.

These findings present empirical evidence for the first time which suggests clinically important changes micro spring technology and a mass-spring-damper system can make to running footwear, consequently offering an insight into the direction and focus of future footwear design and injury interventions.

7.2 Research limitations

Despite attempts to counteract potential limitations by performing a thorough literature review and assessment of previous studies, as is the case with all research, this work has limitations that should be announced and considered.

The first to highlight would be the unexpected biomechanical sample size reduction experienced in the study exploring the effect of pocketed micro spring technology on runners with knee pain, outlined in chapter 6.2. Due to an equipment malfunction only 5 sets of biomechanical data from the knee pain group were available for analysis, all usable data from the knee pain group came from follow up trials in the second testing session, although the clinical data was complete. Despite being outside the control of the author, it is important to keep this in consideration when reviewing the conclusions from this data. This also meant that no comparison between biomechanical parameters pre and post six week pocketed micros spring intervention could be assessed.

The study was designed to explore immediate and short term changes to biomechanical, pain and comfort measures in response to the new technology. The author was unable to assess whether the changes seen were maintained after removal or continued use of the intervention or whether they have any longer-term benefits. Future work should focus on a more longitudinal evaluation of the technology effects.

In each study outlined in chapters 5 and 6 participants were not blinded to the intervention. Although the specific nature of the intervention was not offered by the researcher, in all cases it was evident which footwear integrated the intervention technology. It is therefore important to recognise the potential influence of social desirability bias. This is a research term that describes the tendency of survey and questionnaire respondents to answer questions in a manner that will be viewed favourably by others. It can take the form of over-reporting "good” responses or under-reporting "bad" responses. In the case of this investigation, it is possible that participants felt an obligation to report reductions in knee pain and improvements in comfort as a result of the opportunity to train in a new set of trainers for 6 weeks. There is very little the author could do to mitigate against this potential bias.

Alternatively, another possibility is that respondents may misreport answers subconsciously, mainly as a result of lack of effort given to answering the question. Effortless answering is likely to lead to reporting positive behaviours and attitudes because such reports are easier (Kaminska and Foulsham, 2013). However, as detailed in chapter 4, all comfort and pain questionnaires used in this study have been independently verified as having high levels of reliability and validity.

As the research evolved and throughout the studies described in chapters 5 and 6, the first 5% of stance phase became the timescale of focus for all biomechanical measures (loading rate, acceleration, angular velocity and jerk). Alongside more traditional measures of force loading such as average vertical loading rate and instantaneous vertical loading rate, a drive for a more detailed exploration of this principle, within a more specific timeframe, led to the continued investigation of this outcome measure. This was to assess the initial shock loading at impact and the effect of lower load impacts on knee injuries. Acknowledged is the relatively small number of data points available in this short timescale. For example, with respect to the laboratory based human running trials, whereby force data was sampled at 2000Hz using a force plate, the number of data points used for analysis was 25. This is based upon a sampling frequency of 2000Hz, a focus on 5% of stance, and an average contact time per foot strike of 0.25 seconds for the participants in this study (2000x0.05x0.25=25). However, with respect to the outdoor human running trials of chapter 6, whereby data was sampled at only 148Hz using the IMU sensors, the number of data points used for analysis was only 3. This is based upon a sampling frequency of 148Hz, a focus on 5% of stance, and an average contact time per foot strike of 0.35 seconds for the group of participants in this study (148x0.05x0.35=25). Unfortunately, 148Hz was the maximum sampling frequency of the IMU sensors available for the research and so could not be increased.

7.3 Recommendations for future research

The following section is structured to discuss the implications of this research for the four main stakeholder groups associated to this thesis; researchers, shoe manufacturers, rehabilitation professionals, and runners.

First considered are researchers. The data collection from this investigation covered a vast range of biomechanical measures with certain parameters chosen for analysis in line with the aims and objectives of this thesis. However, there remains a host of additional data, particularly kinematic data from stage one of this work exploring the enhancement of a mass-spring-damper system, which may provide further insights into current findings. Planned further exploration of the current data set incudes, knee and ankle joint angles and moments from laboratory trials to explore biomechanical control differences when wearing micro spring technology and its relationship to the already established findings.

Within current literature much is discussed as to the characterisation of runners who suffer from knee pain. Frequently quoted is the assumption that the incidence of patellofemoral pain syndrome is higher in female runners than in male runners. A more longitudinal and larger study would allow exploration into whether there are any gender differences with respect to the benefits of wearing pocketed micro spring technology. Other avenues of investigation and interest could include, but are not limited to, average weekly mileage, average running speed and age of footwear.

This thesis focuses on the effect pocketed micro spring technology can have on recreational runners suffering with knee pain. Of particular interest would be an assessment of whether the positive changes in biomechanics, pain and comfort seen with knee pain runners would be replicated in groups of runners suffering from other common running injuries such as plantar fasciitis, achilles tendinitis, iliotibial band syndrome etc.

Work within this thesis was subjected solely to traditional methods of statistical analysis such as t-tests and ANOVAs. It is recommended that future research should pursue alternative methods of analysis. One example which may prove enlightening is the use of Statistical Parametric Mapping (SPM) which is a statistical technique originally created by Karl Friston in 1991 for examining differences in brain activity recorded during functional neuroimaging experiments using neuroimaging technologies that has since been adapted by Todd Pataky in 2014 to create a software package specific for one dimensional series.

Many classes of biomechanical data are smooth and contained within discrete bounds and as such are well suited to SPM analyses. SPM applies common statistical techniques on time series so that no information is lost to scalar extractions. It is important to consider that any differences in a kinetic data series, such as ground contact in running, are not necessarily located around, or limited to, the minima or maxima of time series. SPM calculates the test statistic of interest on every point in the time series, but instead of computing a p-value for every point inferential statistics are based on Random Field Theory. This technique would make it possible to use the entire dataset.

There are a number of findings within this thesis that could be of particular interest to shoe manufacturers. Yet to be fully investigated is the true scope of possibilities and variances associated to integrating a mass-spring-damper system into sports footwear. The mass-spring-damper system discussed in this thesis would be recognised in engineering terms as an ‘in series’ arrangement. In other words, the mass (the runner), the spring, and the damper (the shoe midsole) are all arranged within the structure one above another (in series). Within the field of engineering, it is widely recognised that an ‘in parallel’ arrangement is a much more effective mechanical mechanism of dampening impacts. This would see the damper (the shoe midsole) integrated on the same level as the springs. One way to achieve this would be to house EVA foam, or equivalent damper material, within the centre of the pocketed micro springs and explore the effectiveness of such a solution in further improving biomechanical variables, pain and comfort scores. The limiting factor of exploring the explained system within this thesis was the extensive technical development and production machinery modifications that would be needed to achieve this. However, continued innovation developments within this area of industry would suggest such a technological advancement is not beyond reach.

Other variations not explored within this thesis but that carry potential of interesting findings would be an investigation into the influence of differing spring placements. Restrictions related to shoe manufacture meant that pocketed micro springs were placed in separate rearfoot and forefoot cavities within the midsole. Identifying a way to integrate pocketed micro springs into the midfoot as well may have a bearing on the footwear's effectiveness. It is sensible to make the presumption that one footwear design is not equally suited to all wearers. Exploration into engineering variable spring rate properties based on a runner's weight, strike pattern, and activity type could potentially lead to developing a mass-spring-damper solution with the ability to significantly alter biomechanical parameters, comfort ratings and pain levels of any runner.

The idea of bespoke footwear is becoming increasingly popular, as demonstrated by the very recent introduction of 3-D printed running shoes. Last year New Balance announced the limited commercial availability of the Zante Generate running shoe with a 3D printed midsole, selling for $400. New Balance are using a process called selective laser sintering. A machine spreads out a fine layer of powder, then a laser passes over the surface, melting the area that will ultimately become the finished midsole. The process is repeated as the part is fused together one thin layer at a time. Alongside continuing to explore and develop new technologies, there may be scope for shoe manufacturers to revisit more traditional existing technologies, such as springs, and investigate the potential improvements and modernisation recent innovations can bring.

With regards to rehabilitation professionals, chapter 6 observed significant and meaningful changes in pain and comfort scores amongst recreational runners with knee pain when wearing pocketed micro spring technology, yet this was only assessed over a six-week period. It is important that future work establish if these pain and comfort improvements can be maintained. This could be achieved by initiating a six month follow up with the subjects from the current study or by initiating a more longitudinal and larger study.

Identifying a sole cause of knee pain in runners is difficult and is often led by scientific assessment leading to the prescription of either strengthening exercises, orthotic insoles or/and reduced mileage training programmes. One particular theme researched in this work is the importance of comfort amongst pain sufferers. Findings from this research show that as comfort levels increased, biomechanical parameters whereby higher values are seen as risk factors for injury reduced. It could be that increasing comfort changes biomechanical patterns or, it is also possible that changes in a runner's biomechanics can lead to improvements in comfort, the direction of any possible causal relationship was not established in this thesis. However, worthy of consideration for rehabilitation professionals is the potential influence of footwear comfort on knee pain.

And finally, a consideration for recreational runners, with the recommendation being research itself. As described in chapter 2, running shoe manufacturers put a lot of resource and effort into successful marketing campaigns. It is important that runners keen to avoid injury or discomfort look beyond advertisement and explore the key differences between footwear options. This thesis has demonstrated that an openness to trying a unique technology outside the industry norm may be beneficial.

7.4 Final conclusions

This thesis was designed to meet a series of aims and objectives defined in section 1.4.

The research conducted during this thesis identified that pocketed micro spring technology can be viably and effectively integrated into a commercial branded running shoe. A running shoe with a mass-spring-damper system in the midsole now exists as a result of the following key contributions:

- development of a pocketed micro spring capable of reducing impact forces
- quantification of the benefits of this technology through the testing outlined
- established a commercial partnership to develop usable final product

This thesis also explored the effect of the technology on recreational runners currently suffering with knee pain. The research conducted identified that:

- wearing running shoe integrating pocketed micro springs led to reductions in the majority of biomechanical parameters assessed for both healthy and knee pain populations
- internal rotation angular velocity of the tibia at impact and vertical jerk at impact in particular are clinically important variables

- recreational runners currently suffering with knee pain were recorded as feeling lower levels of pain and greater levels of comfort when wearing and training in pocketed micro spring technology

To conclude, reducing impact loading through the use of spring technology has shown to have a positive effect on reducing knee pain in recreational runners.

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APPENDICIES

Appendix A – Ethical Approval

10 August 2015

Jim Richards / Melissa Sutcliffe
School of Health Sciences
University of Central Lancashire

Dear Jim / Melissa

Re: STEMH Ethics Committee Application Unique Reference Number: **STEMH 345**

The STEMH ethics committee has granted approval of your proposal application '**Exploring the biomechanical parameters and knee pain/comfort scores of running in different sports shoe designs**'. Approval is granted up to the end of project date* or for 5 years from the date of this letter, whichever is the longer.

It is your responsibility to ensure that

- the project is carried out in line with the information provided in the forms you have submitted
- you regularly re-consider the ethical issues that may be raised in generating and analysing your data
- any proposed amendments/changes to the project are raised with, and approved, by Committee
- you notify roffice@uclan.ac.uk if the end date changes or the project does not start
- serious adverse events that occur from the project are reported to Committee
- a closure report is submitted to complete the ethics governance procedures (Existing paperwork can be used for this purposes e.g. funder's end of grant report; abstract for student award or NRES final report. If none of these are available use e-Ethics Closure Report Proforma).

Yours sincerely

Paola Dey
Deputy Vice Chair
STEMH Ethics Committee

* for research degree students, this will be the final lapse date

NB - Ethical approval is contingent on any health and safety checklists having been completed, and necessary approvals as a result of gained.

Appendix B – Consent Form

Participant Identification Number:

CONSENT FORM

Title of Project: Exploring the biomechanical parameters and knee pain/comfort scores of running in different sports shoe designs.

Name of Researchers: Melissa Sutcliffe, Professor Jim Richards, Professor James Selfe

MSutcliffe1@uclan.ac.uk JRichards@uclan.ac.uk JSelfe1@uclan.ac.uk

Please read and initial each statement to indicate your agreement.

Please initial box

I confirm that I have read and understood the participant information for the above study and have had any questions answered satisfactorily. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

I have fully completed the health screening questionnaire. ☐

I agree to take part in the above study. ☐

I agree to my data being anonymised and used within any reports, publications or presentations about this work. ☐

__________________ Name of Participant	____________ Date	_______________ Signature
__________________ Name of Person taking consent (If different from researcher)	____________ Date	_______________ Signature
__________________ Researcher	____________ Date	_______________ Signature

KOOS KNEE SURVEY

Today's date: ______/______ /_____ Date of birth: ______ /______ /______

Name: ____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

Symptoms

These questions should be answered thinking of your knee symptoms during the **last week.**

S1. Do you have swelling in your knee?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S3. Does your knee catch or hang up when moving?

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

S4. Can you straighten your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

S5. Can you bend your knee fully?

Always	Often	Sometimes	Rarely	Never
☐	☐	☐	☐	☐

Stiffness

The following questions concern the amount of joint stiffness you have experienced during the **last week** in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

S7. How severe is your knee joint stiffness after sitting, lying or resting **later in the day**?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Pain

P1. How often do you experience knee pain?

Never	Monthly	Weekly	Daily	Always
☐	☐	☐	☐	☐

What amount of knee pain have you experienced in the **last week** during the following activities?

P2. Twisting/pivoting on your knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P3. Straightening knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P4. Bending knee fully

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P5. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P6. Going up or down stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P7. At night while in bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P8. Sitting or lying

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

P9. Standing upright

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A1. Descending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A2. Ascending stairs

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities, please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A4. Standing

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A5. Bending to floor/pick up object

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A6. Walking on flat surface

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A7. Getting in/out of car

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A8. Going shopping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A9. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A10. Rising from bed

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A11. Taking off socks/stockings

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A12. Lying in bed (turning over, maintaining knee position)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A13. Getting in/out of bath

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A14. Sitting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A15. Getting on/off toilet

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

For each of the following activities, please indicate the degree of difficulty you have experienced in the **last week** due to your knee.

A16. Heavy domestic duties (moving, heavy boxes, scrubbing floors, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

A17. Light domestic duties (cooking, dusting, etc)

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Function, sports and recreational activities

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experience during the **last week** due to your knee.

SP1. Squatting

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP2. Running

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP3. Jumping

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP4. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

SP5. Kneeling

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Quality of life

Q1. How often are you aware of your knee problem?

Never	Monthly	Weekly	Daily	Constantly
☐	☐	☐	☐	☐

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all	Mildly	Moderately	Severely	Totally
☐	☐	☐	☐	☐

Q3. How much are you troubled with lack of confidence in your knee?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

Q4. In general, how much difficulty do you have with your knee?

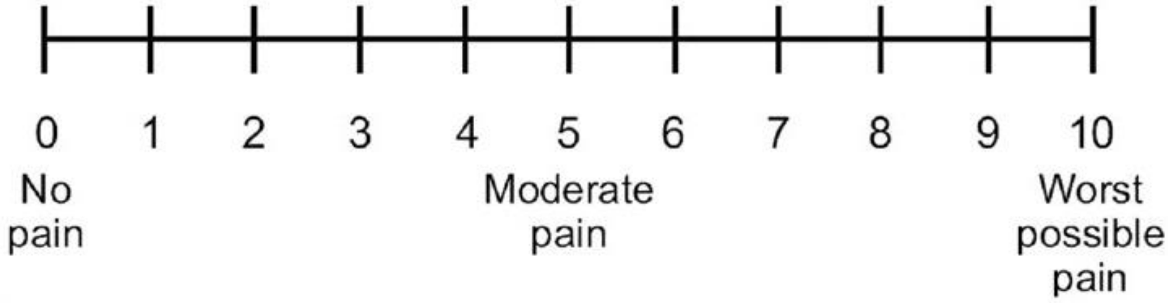
None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

Thank you very much for completing all the questions in this questionnaire.

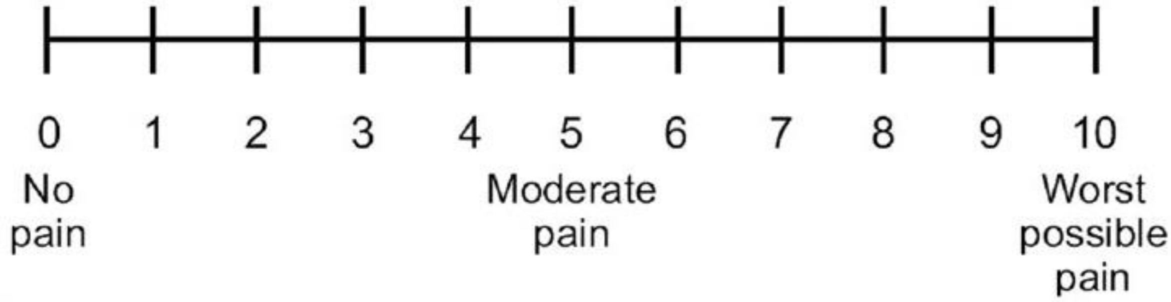
Appendix D – NPRS Questionnaire

NUMERIC PAIN RATING SCALE

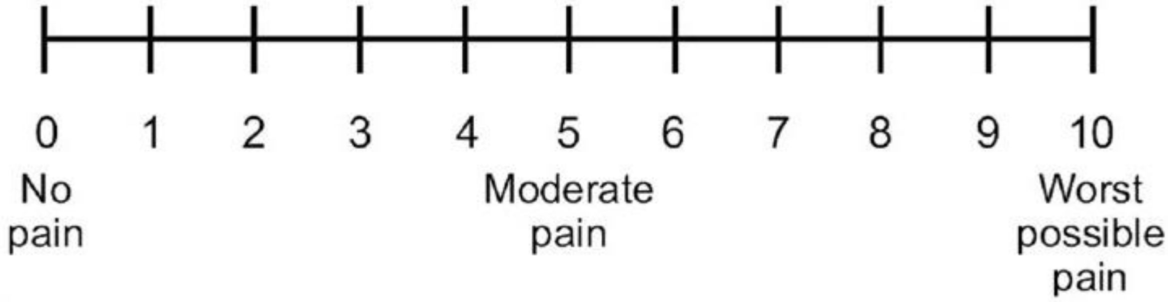
1. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your **USUAL** level of knee pain when running.



2. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your knee pain during the trial with your **REGULAR RUNNING SHOE.**



3. On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your knee pain during the trial with your **TEST RUNNING SHOE.**



Appendix E – Comfort Questionnaire

COMFORT QUESTIONAIRE

1. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **OVERALL COMFORT** of your **REGULAR RUNNING SHOE**.

Not comfortable at all — Most comfortable condition imaginable

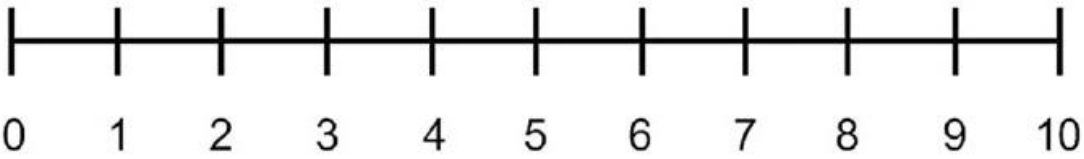
2. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **HEEL CUSHIONING** of your **REGULAR RUNNING SHOE**.

Not comfortable at all — Most comfortable condition imaginable

3. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **FOREFOOT CUSHIONING** of your **REGULAR RUNNING SHOE.**

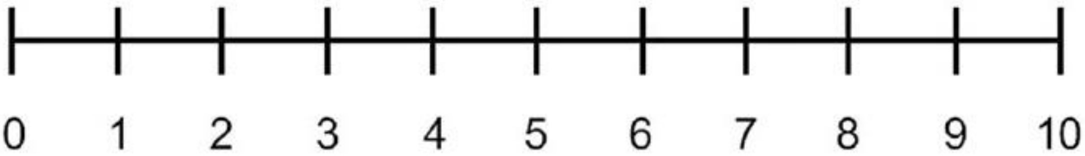
Not comfortable at all — Most comfortable condition imaginable

4. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **OVERALL COMFORT** of the **TEST RUNNING SHOE.**



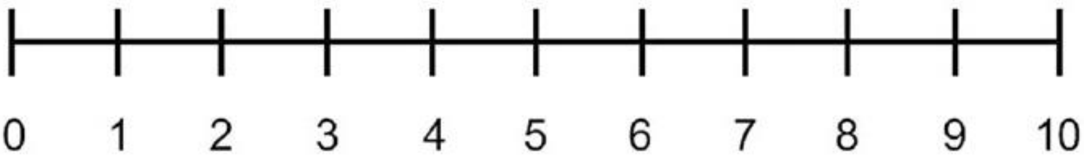
Not comfortable at all | Most comfortable condition imaginable

5. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **HEEL CUSHIONING** of the **TEST RUNNING SHOE.**



Not comfortable at all | Most comfortable condition imaginable

6. On a scale of 0 to 10, with 0 being not comfortable at all and 10 being the most comfortable condition imaginable, how would you rate the **FOREFOOT CUSHIONING** of the **TEST RUNNING SHOE.**



Not comfortable at all | Most comfortable condition imaginable

Appendix F – Spring Rate Assessment

IST
INSTITUTE of SPRING TECHNOLOGY

INSTITUTE OF SPRING TECHNOLOGY LTD
Henry Street, Sheffield, S3 7EQ United Kingdom
Tel: +44 (0)114 276 0771 Fax: +44 (0)114 252 7997
Email: ist@ist.org.uk Internet: www.ist.org.uk

TEST CERTIFICATE

UKAS 0386

CLIENT : HARRISON SPINKS BEDS Ltd Westland Road Leeds LS11 5SN	**CERTIFICATE NUMBER** : 013513
	IST JOB NO. : 015639Q
CONTACT : Melissa Sutcliffe	**ORDER NO.** : Email 30/04/14
	Page No 1 of 2

SAMPLE IDENTITY

TEST COMPLETION DATE : 1st May 2014

TEST PROCEDURE : Load tested to documented in house method OI 28 issue 5.

Load Test

Each springs free height was measured. The springs were then tested in accordance with BS1726 part 1 section 5.3.2.1 where springs are tested at 20% and 80% of the safe deflection from the nominal free length of the spring, and then the spring rate recorded.

Rate N/mm
5.092

Approved by:

~~A. May~~ ~~Managing Director~~ P.B. Batty Testing Services Manager ~~M. O'Malley~~ ~~Membership Services Manager~~ ~~C.J. Rushton~~ ~~Engineering Manager~~

on behalf of IST Date: 9th May 2014

Appendix G – Intersport IC P1.0 marketing materials


P. 1-0
59€99
RÉF. 232436
PRO TOUCH
Conçue pour les coureuses occasionnelles à régulières recherchant en priorité le confort et l'amorti.
Tige mesh* avec renforts synthétiques - Semelle extérieure caoutchouc - Semelle intérieure textile - Doublure textile
POINTURES : du 36 au 42
POIDS : 296 g en 38
Amorti
Légèreté
Confort
ROUTE
SENTIER
AMORTI AV / AR
E-springs
DÉROULÉ DYNAMIQUE


La P1.0, la nouvelle expérience running Pro Touch
Réduction des coutures sur la tige de sorte à apporter un confort optimal
Une tige textile aérée et respirante pour plus de confort
Semelle intermédiaire en EVA
La mousse cellulaire ortholite® est très légère et « respirante » ce qui permet une bonne aération et l'élimination d'excès de chaleur et d'humidité pour un confort optimal.
Technologie qui permet une excellente absorption des chocs, tout en libérant l'énergie emmagasinée lors de la phase de poussée
Semelle intermédiaire en EVA + double densité talon
Plaque TPU
PRO GRIP
Semelle extérieure offrant une excellente adhérence sur toutes les surfaces
PRO FLEX
Des cannelures souples pour une flexibilité maximum au niveau de l'avant du pied
PRO TOUCH
CHAUSSURE FEMME

Health Screening Questionnaire

University of Central Lancashire

Name: .... D.O.B................................

Emergency Contact Details: ....

Prior to participating within the study you are required to complete a health screening questionnaire to ensure you are able to partake in physical activity and eligible for the study.

Please tick the appropriate box:	YES	NO
Q1 Has your doctor ever said you have a heart condition and/or should only participate in medically supervised physical activity?	☐	☐
Q2 Do you ever feel pain in your chest during physical activity?	☐	☐
Q3 Have you experienced chest pains when not doing physical activity?	☐	☐
Q4 Do you suffer with palpitations?	☐	☐
Q5 Do you experience dizziness or fainting?	☐	☐
Q6 Have you ever been told you have high blood pressure or are you taking medication for blood pressure or any other heart condition?	☐	☐
Q7 Do you have any existing bone or joint problem that could be made worse by physical activity?	☐	☐
Q8 Do you experience shortness of breath during only mild exertion?	☐	☐
Q9 Do you suffer from either Asthma or Diabetes Mellitus?	☐	☐
Q10 Are you currently taking any prescribed medication we need to be made aware? If so, what? ………………………………………………………………………………	☐	☐
Q11 Are you pregnant or have you given birth in the last 6 weeks?	☐	☐
Q12 Have you recently undergone surgery or are you carrying an injury?	☐	☐
Q13 Are you allergic to tape being applied to the skin?	☐	☐
Q14 Are you aware of any other reasons why you should not participate in physical exercise? If so, what?……..……………………………………	☐	☐

Signed..................... Date...........................

Appendix I – Individual comfort rating scores

Healthy Group

Subject	First Session					
	Regular Running Shoes			P1.0s		
	Overall	Heel	Fore	Overall	Heel	Fore
1	8	8	8	8	9	7
2	4	3	4	9	10	9
3	7	7	7	8	7	9
4	5	5	5	10	9	9
5	6	5	6	8	8	8
6	7	8	5	8	8	9
7	5	5	5	7	7	7
8	7	7	8	10	10	9
9	6	4	7	5	7	5
10	8	7	8	7	9	7
11	8	9	7	8	9	7
12	7	6	7	8	7	9
13	7	6	7	8	8	8
14	8	7	7	9	9	9
15	7	7	7	8	9	8
16	1	1	2	9	9	8
17	10	10	10	5	5	6
18	5	5	6	9	9	8
19	7	6	6	7	7	8

Knee Pain Group

Subject	First Session					
	Regular Running Shoes			P1.0s		
	Overall	Heel	Fore	Overall	Heel	Fore
1	8	7	7	7	6	6
2	8	7	7	7	7	7
3	6	7	7	8	8	8
4	8	6	7	9	9	9
5	7	7	6	7	7	7
6	8	8	8	7	8	8
7	8	7	7	9	8	7
8	3	5	1	8	8	8
9	6	5	5	9	10	10
10	5	5	5	6	6	6
11	8	7	7	7	7	7

Appendix I – Individual comfort rating scores

Subject	Second Session					
	Regular Running Shoes			P1.0s		
	Overall	Heel	Fore	Overall	Heel	Fore
1	7	7	6	7	7	8
2	9	8	8	9	9	9
3	6	5	6	7	7	7
4	6	5	5	9	10	9
5	8	8	8	8	8	8
6	7	7	6	7	8	7
7	N/A	N/A	N/A	N/A	N/A	N/A
8	6	4	5	8	8	8
9	2	2	1	9	9	9
10	N/A	N/A	N/A	N/A	N/A	N/A
11	N/A	N/A	N/A	N/A	N/A	N/A

Appendix J – Individual NPRS scores

Knee Pain Group

Subject	First Session			Second Session		
	General	Regular	P1.0s	General	Regular	P1.0s
1	5	5	5	2	2	0
2	4	1	1	2	2	2
3	3	3	2	4	3	4
4	7	1	1	2	3	0
5	2	2	2	2	2	2
6	7	5	6	3	3	3
7	3	3	2	N/A	N/A	N/A
8	7	5	1	7	7	4
9	4	4	2	0	0	0
10	4	4	4	N/A	N/A	N/A
11	6	6	4	N/A	N/A	N/A

Appendix K – Individual KOOS scores

Knee Pain Group

Subject	First Session				
	KOOS Pain	KOOS Symptom	KOOS ADL	KOOS Sport/Rec	KOOS QOL
1	58.33	85.71	80.88	50.00	56.25
2	88.89	78.57	100.00	80.00	75.00
3	66.67	75.00	97.06	50.00	56.25
4	58.33	71.43	61.76	25.00	50.00
5	72.22	57.14	76.47	70.00	68.75
6	50.00	42.86	66.18	20.00	18.75
7	77.78	78.57	82.35	60.00	62.50
8	69.44	57.14	70.59	60.00	62.50
9	83.33	67.86	91.18	85.00	68.75
10	75.00	85.71	91.18	35.00	37.50
11	72.22	50.00	80.88	55.00	56.25

Subject	Second Session				
	KOOS Pain	KOOS Symptom	KOOS ADL	KOOS Sport/Rec	KOOS QOL
1	80.56	82.14	86.76	50.00	62.50
2	97.22	82.14	98.53	80.00	81.25
3	77.78	67.86	95.59	75.00	62.50
4	83.33	85.71	91.18	65.00	75.00
5	75.00	64.29	89.71	75.00	68.75
6	61.11	60.71	73.53	50.00	43.75
7	N/A	N/A	N/A	N/A	N/A
8	69.44	67.86	70.59	60.00	68.75
9	100.00	100.00	100.00	100.00	100.00
10	N/A	N/A	N/A	N/A	N/A
11	N/A	N/A	N/A	N/A	N/A