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The Development and Evaluation of a Dynamic Elastomeric Fabric Orthosis to Support the Management of Athletic Pelvic / Groin Injury

by

LEANNE SAWLE

A thesis submitted to Plymouth University in partial fulfilment for the degree of

DOCTOR OF PHILOSOPHY

School of Health Professions

Faculty of Health and Human Sciences

Plymouth University

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Abstract

Name Leanne Sawle

Title The Development and Evaluation of a Dynamic Elastomeric Fabric Orthosis (DEFO) to Support the Management of Athletic Pelvic / Groin Injury.

Athletic pelvic / groin injuries can be difficult to define, diagnose and therefore manage. These injuries are often the result of multifactorial dysfunction, making them susceptible to becoming chronic. Transverse pelvic belts have shown effectiveness in reducing pain and improving function in athletes with pelvic / groin pain, but there may be better alternatives. Exploring different pelvic belt configurations with athletes with pelvic / groin pain confirmed the role of a transverse belt but also found that diagonal belts produced significantly (<0.05) greater effects upon clinical measures of pain and function.

Dynamic elastomeric fabric orthoses (DEFOs) are Lycra®-based orthoses theorised as providing stability and enhancing proprioception. A DEFO was designed to apply diagonal force to the pelvic girdle and mimic transverse belt application. In a series of single case studies the DEFO was found to have beneficial effects upon pain and / or function in selected athletes with pelvic / groin pain. Athletes’ subjective reports suggested that balance and power may have also been positively influenced. Further work exploring appropriate measures of athletic balance led to the investigation of the intra-rater reliability of a functional measure; the multiple single-leg hop-stabilisation test. Good to excellent reliability (ICC = 0.85; CI 0.61-0.90) confirmed this measure as being reliable for use in a future study, and highlighted relationships with other factors such as age and training status.
The findings of a pilot RCT indicated that with minor revisions this protocol could be effectively implemented in informing a future RCT. Findings also indicated that the DEFO led to moderate to large effect sizes on clinical measures ($d = 0.6-1.1$) of active straight leg raise and squeeze test force, and negligible to small effects on measures of power and functional balance ($d = 0.1-0.3$). This thesis therefore outlines the development and initial evaluation of a novel DEFO for supporting the management of athletic pelvic / groin injury. Further work is required to undertake a fully powered RCT, and to explore the mechanistic action of this DEFO.
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<th>Description</th>
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<tr>
<td>AMED</td>
<td>Allied and Complimentary Medicine Database</td>
</tr>
<tr>
<td>ASIS</td>
<td>Anterior Superior Iliac Spine</td>
</tr>
<tr>
<td>ASLR</td>
<td>Active Straight Leg Raise</td>
</tr>
<tr>
<td>BESS</td>
<td>Balance Error Scoring System</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
</tr>
<tr>
<td>CM</td>
<td>Centimetres</td>
</tr>
<tr>
<td>DEFO</td>
<td>Dynamic Elastomeric Fabric Orthosis</td>
</tr>
<tr>
<td>DIV</td>
<td>Doppler Imaging of Vibrations</td>
</tr>
<tr>
<td>E.G</td>
<td>Exempli Gratia</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>ICC</td>
<td>Intraclass Correlation Coefficient</td>
</tr>
<tr>
<td>I.E</td>
<td>Id Est</td>
</tr>
<tr>
<td>IO</td>
<td>Internus Obliquus</td>
</tr>
<tr>
<td>KG</td>
<td>Kilograms</td>
</tr>
<tr>
<td>LS</td>
<td>Leanne Sawle (Investigator)</td>
</tr>
<tr>
<td>M</td>
<td>Mean (refers only to the equation in figure 7.2)</td>
</tr>
<tr>
<td>M</td>
<td>Metres</td>
</tr>
<tr>
<td>MM</td>
<td>Millimetres</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>MSLHST</td>
<td>Multiple Single-Leg Hop-Stabilisation Test</td>
</tr>
<tr>
<td>N</td>
<td>Newtons</td>
</tr>
<tr>
<td>PSIS</td>
<td>Posterior Superior Iliac Spine</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>SDD</td>
<td>Smallest Detectable Difference</td>
</tr>
<tr>
<td>SEM</td>
<td>Standard Error of Measurement</td>
</tr>
<tr>
<td>SIJ</td>
<td>Sacroiliac Joint</td>
</tr>
<tr>
<td>SIJD</td>
<td>Sacroiliac Joint Dysfunction</td>
</tr>
<tr>
<td>SL</td>
<td>Sarah Lay (Pilot RCT Study Administrator)</td>
</tr>
<tr>
<td>TrA</td>
<td>Transversus Abdominis</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
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<td>YRS</td>
<td>Years</td>
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To all of the physiotherapists and athletes who were the backbone of study recruitment and participation, thank you for your valuable time and your enthusiasm.

Finally I’d like to thank my parents and brother for their practical support during the undertaking of this work.
Author Declaration

At no time during the registration for the degree of Doctor of Philosophy have I, Leanne Sawle, been registered for any other University award without the prior agreement of the Graduate Committee.

Work submitted for this research degree at the Plymouth University has not formed part of any other degree either at Plymouth University or at another establishment. This work is my own.

Whilst undertaking this work I have attended relevant training courses within and outside of Plymouth University. These include research methods, writing skills, risk assessment, Good Clinical Practice (GCP) training, systematic searching of literature and physiotherapy based training. I have submitted my work for both poster and oral presentation at National and International conferences, and I have also published work in peer reviewed journals.

During the time spent undertaking this thesis I was employed as an associate in a Knowledge Transfer Partnership between Plymouth University and DM Orthotics Ltd (January 2009-August 2010), and was subsequently employed by DM Orthotics (September 2010 – September 2015).

Thesis Word Count: 61, 174

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Leanne Sawle Date
List of Conferences and Published Abstracts


Sawle, L. et al (2013). Developing a dynamic elastomeric fabric orthosis (DEFO) to aid in the management of athletic pelvic pain


List of Peer Reviewed Papers Published


Chapter One Introduction

The purpose of chapter 1 is to provide a rationale for the work undertaken in this thesis. It is based on a systematic search of the current literature base. This chapter will introduce and appraise the current literature on pelvic / groin injuries, athletic pelvic / groin conditions, definitions, anatomy, aetiology, incidence, injury mechanisms, physiotherapeutic treatment strategies, pelvic belts and dynamic orthotics.

The aim of this thesis is identified at the end of the chapter, and is based upon defined gaps in the literature. Specific objectives are outlined for the proceeding chapters.

1.1 Sports Injuries

Injuries within sport are well documented (Brooks et al., 2005; Brown et al., 1999; Malliou et al., 2004). Although the rate, site and mechanism of injury varies according to the nature of the sport, contact sports like rugby union report high rates of injury (Quarrie et al., 2001), which can have considerable impacts upon both players and clubs. For example the UK Rugby Premiership reports an injury rate of 1.8 injuries per club for each match played, with the injury severity leading to an average of 26 days before returning to play (Rugby Football Union, 2015).

Whilst sports injuries are commonplace, certain injuries are more challenging to manage than others. Athletic pelvic / groin injuries are, for many reasons, one such example (Ficek et al., 2008), and will therefore be explored in the following work.

To identify the relevant literature in this field a systematic approach was used to search Cinahl, Medline and Amed databases via EBSCO. The following limits were used: the search terms appeared in the abstract of academic journal articles, written in English and published from 1990-September 2015; the articles focused on the adult population.
Key words were identified in order to answer questions on types of injury, assessment techniques, treatment approaches, epidemiological and aetiological characteristics. These terms were categorised in order to build search strategies (table 1.1):

1. Athlet* OR sport* OR player* AND pelvi* OR groin OR adduct* OR sacroiliac OR osteitis pubis OR athletic pubalgia AND pain OR injur* OR dysfunction* OR strain*
2. Test* OR evaluation* OR measure* OR assess* OR diagnos*
3. Treatment* OR intervention* OR therap* OR program* OR pelvic belts OR exercis*
4. Incidence* OR prevalence* OR epidemiolog* OR aetiolog*

<table>
<thead>
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<th>Item Number</th>
<th>Item</th>
<th>Strategy</th>
<th>Results</th>
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<tr>
<td>1</td>
<td>Types of athletic pelvic / groin injury</td>
<td>1</td>
<td>175</td>
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<td>2</td>
<td>Evaluation of athletic pelvic / groin pain</td>
<td>1 and 2</td>
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<td>4</td>
<td>Epidemiology and aetiology of athletic pelvic / groin injury</td>
<td>1 and 4</td>
<td>32</td>
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<tr>
<td></td>
<td>Total</td>
<td></td>
<td>440</td>
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Table 1.1 Search terms and strategies employed

The reference lists of articles were also hand searched to gather further sources including doctoral theses and key theoretical texts, and have been used to underpin the following discussion.
1.2 Defining Pelvic / Groin Pain

Defining pelvic / groin pain is confounded by the lack of consensus with the terminology used (Zoga et al., 2008; Olsson, 2010). The European Guidelines for the Diagnosis and Treatment of Pelvic Girdle Pain (Vleeming et al., 2008) separates the lumbar region from the pelvic girdle by recognising pelvic girdle pain as occurring between the gluteal fold and posterior superior iliac spine (PSIS), and / or involving the symphysis pubis and radiation into the posterior thigh. As a result there are several potential sources of pain within the pelvic / groin region including the sacroiliac joint (SIJ), symphysis pubis, pubic rami, pelvic floor and abdominal muscles, nerves, bursa, fascia and ligamentous structures. Pain can also be referred from structures including the hip and lumbar spine (Tibor and Sekiya, 2008).

Groin pain may appear to be an anterior pelvic region presentation, but distinguishing between groin and SIJ pain can be difficult when there is an overlap in the symptomology. Posterior pelvic pain (a label for SIJ pain) is commonly located around the PSIS, but can also be experienced in the groin (Prather and Hunt, 2004). Adaptive changes caused by conditions such as symphysis pubis dysfunction can lead to SIJ pain, therefore the reverse is possible. There may also be more than one site of pain (Hureibi and McLatchie, 2010; Morelli and Smith, 2001), and an overlap in responses to established pain provocation tests that are used to aid diagnosis. Furthermore, findings have shown that both adductor dysfunction and osteitis pubis often coexist in footballers (Cunningham et al., 2007), and athletes with long-standing adductor related pain may also present with posterior pelvic pain (Mens et al., 2006a). Therefore caution should be taken in using absolute terms in defining pelvic / groin pain, and they should be considered as sharing a common dysfunction within the kinetic chain of the adductor, pelvis and abdominal regions (Jansen et al., 2008).
For the purpose of this thesis the generic term of pelvic / groin pain will be used to group these musculotendinous conditions, and in line with Olsson (2010) will be considered as self reported pain in the pelvic / groin region.

1.3 Anatomy of the Pelvic / Groin Region

An understanding of the anatomy of the pelvic / groin region helps to clarify why there is a lack of consensus about the definition of pelvic / groin pain.

The pelvic girdle is comprised of many interdependent anatomical structures; including bilateral sacroiliac joints, and the centrally located symphysis pubis. Articulations with the lumbar spine and femoral heads means that the pelvic / groin region acts as a substantial load bearing structure, transferring upper body forces to the lower limbs (Palastanga et al., 2002). Loads are transferred through the spine to the pelvis via the SIJ, making stability a key component of effective function. Forces are also exerted by the pubis originating adductor muscles, whilst a complex array of ligamentous and muscular structures act upon the pelvic girdle to both stabilise and allow movement. This musculature has been recognised as providing a compressive force to aid pelvic / groin stability through efficient force closure (Lee, 2001). Force closure relates to the role of muscles in actively providing stability to a joint (Hodges, 2004), and is discussed further in section 1.5.

A model proposed by Bergmark (1989) theorised that there are both local and globally situated muscle systems acting to stabilise the spine. This has been developed into work presenting them as sling systems, connected by fascial and ligamentous structures (Lee, 2004) and contributing to pelvic stability. Figure 1.1 identifies the components of these slings.
Four muscle slings have been identified as being responsible for pelvic stability; the anterior oblique, posterior oblique, longitudinal and lateral slings; the latter being more concerned with hip stability (Lee, 2004). They comprise of “chains” of muscles that produce a sling of forces, that aid in the loading process by means of indirectly affecting compression in the lumopelvic region (Lee, 2004). It is theorised that these structures act in unison for optimal function, therefore any impairment to these slings will have a detrimental influence upon pelvic / groin stability. Hodges (2004) elaborated upon this notion of stability highlighting the role that these muscles play in feed forward and feedback mediated motor control strategies. These strategies enable pelvic / groin stability to be maintained in different conditions; the feedforward system operating when an action is predictable, or the feedback system responding to unpredictable forces (Hodges, 2004). These motor control strategies play an important role in pelvic / groin stability, and will be discussed further in chapter 3.

<table>
<thead>
<tr>
<th>System</th>
<th>Muscles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior Oblique</td>
<td>Latissimus dorsi, gluteus maximus and the intervening thoracodorsal fascia</td>
</tr>
<tr>
<td>Anterior Oblique</td>
<td>External oblique and contralateral internal oblique (OI) and the intervening anterior abdominal fascia, contralateral adductors of the thigh (contralateral to the external oblique)</td>
</tr>
<tr>
<td>Longitudinal</td>
<td>Erector spinae, deep laminae of the thoracodorsal fascia, sacrotuberous ligament, biceps femoris</td>
</tr>
<tr>
<td>Lateral</td>
<td>Gluteus medius and minimus, tensor fascia lata and contralateral adductors of the thigh</td>
</tr>
</tbody>
</table>

Figure 1.1 Components of the muscle slings. Reproduced from Lee (2001)
1.4 Aetiology of Pelvic / Groin Pain

The previous discussion has highlighted that there are many interdependent structures which can contribute to pelvic / groin pain. Several theories of dysfunction are regularly cited in connection with pelvic / groin injury, and demonstrate a relationship with models of spinal stability.

A landmark model of spinal stability and the subsequent development of exercise programmes for low back pain patients, was made with the identification of three dependent, and well co-ordinated subsystems (Panjabi, 1992a); active (muscles), passive (discs and joints) and neural (central nervous system and nerves). Non-optimal functioning in any subsystem (arising from operating outside of normal limits of range and load) was theorised to result in three responses: compensation in other subsystems to maintain normal functioning, long term adaptation allowing normal function but with an adapted stability system, or injury/pain resulting from dysfunction.

The Integrated Model of Function (Lee and Vleeming, 1998) shows a similar recognition of the role of subsystems for optimal functioning (figure 1.2 presents this model). Dysfunction and instability can occur when any one of the following components in this model are disrupted: form closure (stability deriving from the anatomy of joints and their ligamentous structures), force closure (stability deriving from local myofascial tissues), motor control (muscle forces derived from feedforward/feed backward control) or emotion/ awareness.
Figure 1.2 The Integrated Model of Function (Lee and Vleeming, 1998)

Figure 1.3 is an interpretation of how the components of this model can also be seen to impact upon each other. It builds upon the proposal of Lee (2001) that any problem is either due to a restriction in movement or poor control of movement i.e. instability.
Figure 1.3 Causes and effects of instability and its relationship with pelvic / groin dysfunction.
This schematic (figure 1.3) highlights that neural and physiological influences can contribute to motor control (Hodges, 2004), whilst pain and loss of function may also be associated with alterations in force and form closure (Lee, 2001). A loss of force closure (Snijders et al., 1993; Snijders et al., 1998), especially at the SIJ, has often been linked to pelvic / groin dysfunction (Pool-Goudwaard et al., 1998). In this instance “force closure” represents the muscular forces which contribute to SIJ stability; particularly transverse and oblique muscles (Richardson et al., 2002).

The emotion-related component of the model (Lee and Vleeming, 1998) reiterates the need to understand the individual; that an individual’s perception of pain and /or function can influence any component of the model. This may suggest an emotive influence of previous pelvic /groin pain and increased risk of repeat injury. However, repeat injuries may also reflect the presence of inherent instability. Instability or non-optimal joint stability refers to too much (laxity) or too little (stiffness) joint movement which results in inefficient load transfer (Vleeming et al., 2008). It is associated with poor neuromuscular control, and is derived from the notion that optimal stability is the balance between movement and control (Vleeming et al., 2008).

As a result of these interactions, pelvic / groin dysfunction is represented within figure 1.3 as a presentation concerned with instability and its relationship with form closure, force closure and/or motor control. Deficits in force closure, form closure and motor control may be due to a variety of factors as outlined in figure 1.3; including ligament laxity, proprioceptive deficit, muscular fatigue and/or changes in the control of muscle activation (Cowan et al., 2004; Mens et al., 2001). These changes may result in disordered activity of local muscle stabilizers, as seen with delays in muscle recruitment and sub-optimal movement patterns during postural tasks (Hungerford et al., 2003; Hungerford et al., 2004). The influence of other factors such as pain perception are
recognised, and can be attributed to the emotion / awareness component in the Lee and Vleeming (1998) model.

Alterations in muscle recruitment, morphological changes and lumbopelvic stability have also been implicated in several conditions including low back and pelvic / groin pain (Hungerford et al., 2003; Cowan et al., 2004; Jansen et al., 2009; Hodges, 1999; Hides et al., 1996; Beales et al., 2010; Hirata et al., 2015; Bussey and Milosavljevic, 2015). More specifically delays in the recruitment of local core stabilisers have been observed when patient groups with low back or pelvic / groin pain are compared to healthy controls (Hodges and Richardson, 1999; Cowan et al., 2004; Hides et al., 1996). However more recent motor control work has not confirmed any delay in abdominal muscle feed forward activity (Gubler et al., 2010), and has challenged the action of ‘local’ muscles such as transversus abdominis (TrA) (Morris et al., 2013).

It has also been shown that athletes with long-standing adductor pain have a significantly decreased TrA thickness compared with healthy controls at rest (Jansen et al., 2010a). This suggests that rehabilitation should look to address atrophy and that TrA atrophy could be a factor associated with further risk of groin injury. However, this difference in TrA thickness was not apparent during either the ASLR or squeeze test. This may be explained by the use of muscular compensatory mechanisms, or side to side TrA differences between injured athletes and controls (Jansen et al., 2010a).

Further, no significant difference in TrA or OI thickness from rest to performing an ASLR (percentage change) is seen between SIJ pain patients and healthy controls, regardless of whether a pelvic belt was worn (Brizzolara et al., 2015). Symptom improvements seen from pelvic compression (Beales et al., 2010) suggests that there are other factors influencing pain generation. Pain, for example, could be caused by the loading of muscles and ligaments which a pelvic belt may be able to offloaded (Pel et
al., 2008). It has also been suggested that compression may enhance pelvic stability and thus reduce pain associated with increased instability (Brizzolara et al., 2015). The impact of muscle recruitment (magnitude and timing) on stability and pain is not universally agreed, and has led to different approaches to both research and rehabilitation. Muscle atrophy occurring after the onset of acute low back pain, for example, has been shown to remain after the cessation of pain suggesting it may not have a primary role in pain generation. However, specific, local muscle focused exercise has been shown to be effective in restoring the atrophied multifidus and in reducing associated pain. This suggests the importance of restoring motor control for effective recovery (Hides et al., 1996). More recent work has focused upon the importance of co-ordinated muscle activity for stability and the use of recruitment patterns which constantly alter according to task and load (McGill et al., 2003). Consequently stability may need to be restored through facilitating motor patterning of many muscles rather than focusing upon the activation of single muscles (Kavcic et al., 2004). This may not be dependent upon the use of motor control exercises as Macedo et al., 2012 showed that for chronic low back pain patients motor control exercises were no better than graded activity exercise. Further many exercise programmes have had a tendency to focus upon spinal stabilisation and trA activation during abdominal hollowing. However it has been shown that in comparison to healthy controls, TrA contraction ratio during abdominal hollowing does not clearly identify those with chronic low back pain (Pulkowski et al., 2012). In addition the effective treatment of this patient population has not shown to be correlated with improved function of abdominal muscles (Mannion et al., 2012). In light of a recent systematic review and meta-analysis concluding that strong evidence exists to suggest that active exercise is as effective as spinal stabilisation exercises in effectively treating low back pain (Smith et al., 2014), other factors need to be considered. This may include factors such as tactile
acuity (Luomajoki and Moseley, 2011) and speeding up delayed muscle reflexes (Liebetrau et al., 2013). However as much of this work focuses upon the group effects of rehabilitation programmes, it is suggested that the most effective form of rehabilitation depends on the individual and factors such as pain beliefs, and condition sub groups.

Understanding is further complicated by the fact that pain may cause patients to use different recruitment strategies, and that altered postural control can also result in the development of pain (Hodges and Moseley, 2003). Changes in the action of local stabilisers have also been recorded as a response to anticipated pain (Jansen et al., 2010b). Although this was under the constraints of experimental acute groin pain, a significant decrease in relative TrA and IO muscle thickness was found when healthy participants anticipated pain compared to no pain, and when pain was actually experienced (Jansen et al., 2010b). This suggests that altered muscle responses associated with pain anticipation may therefore influence rehabilitation success.

Despite contradictory findings on the stabilising behaviour of musculature, pelvic / groin injuries appear to be associated with impaired load transfer (Lee, 2001; Bussey and Milosavljevic, 2015). Form and force closure deficits may play a role in impaired load transfer, but other factors such as proprioceptive deficit (Mens et al., 1999; Georgy, 2011) and pain (Jansen et al., 2010a) also appear to impact upon this process and affect motor control.

1.5 Athletic Pelvic/Groin Injury

Athletic pelvic / groin injury is regarded as a common yet challenging phenomenon (Ficek et al., 2008; Harmon, 2007). Its complexity appears to be associated with a variety of issues including the difficulty in identifying the pelvic / groin structures
involved and in determining the variables that contribute to dysfunction (anatomical, biomechanical etc), the lack of a gold standard assessment tool, and the common occurrence of more than one site of pain (Ficek et al., 2008; Quinn, 2010; Micheli and Coady, 1997; Serner et al., 2015). The result is that a clear diagnosis is often problematic, especially when it is difficult to distinguish between conditions like adductor strains and osteitis pubis (Morelli and Smith, 2001; Kinchington, 2012).

Advances have been made by the introduction of a clinical entity approach (Holmich, 2007; Bradshaw et al., 2008), a novel patho-anatomical method of categorising athletic groin conditions (Falvey et al., 2009) and the development of a consensus statement on sportsman’s hernia “inguinal disruption” (Sheen et al., 2014). The recent conclusions drawn by the athletic groin terminology consensus group may contribute even more to defining specific injuries (Weir et al., 2015), by moving away from global terms.

At present the lack of consensus in defining specific conditions means that pelvic / groin pain is often discussed as either a range of conditions, for example adductor injuries, or grouped as being groin pain. Injuries of this nature are frequently discussed in “generic” terms and are not often quantified. Whilst it is acknowledged that the true occurrence of all pelvic and groin injuries is probably underestimated (Cusi, 2010), some attempts have been made to quantify the occurrence of condition types in particular sports (Hölmich et al., 1999; Glasgow et al., 2011).

Differential diagnosis also needs to be considered and influences the eligibility criteria used in the clinical studies in this thesis. Differential diagnosis has been discussed extensively elsewhere (Quinn, 2010; Alomar, 2015). This includes hip pathology which can refer pain into the groin region. In the athletic population this can include diagnoses such as femoro-acetabular impingement (FAI), osteoarthritic changes, fractures, bursitis, contusions and labral tears (Quinn, 2010). Clinical assessment and
investigation should always explore the hip as a source of groin pain, and appreciate that FAI and specific groin conditions are known to coexist. This is apparent from looking at the findings of a recent systematic review which reported the presence of FAI in 12-94% of athletes with diagnoses of adductor pain, athletic pulbagia or sports hernias (Munegato et al., 2015).

Some of the most commonly cited conditions affecting the pelvic / groin region in athletes, the tests used to diagnose them, and management techniques used will be presented (figure 1.4). These conditions will be discussed in greater detail throughout the chapter, and are representative of the patient population recruited for this thesis.
Adductor Muscle / Tendon Pain.

Pain affects the adductor muscle group and tendons. Chronic adductor longus tendonopathy is the most common presentation; other diagnoses include ruptures and strains. Acute adductor pain can result from trauma. Longstanding pain in this area is commonly referred to as adduction-related pain, indicating that this pain does not always involve tendonitis but is provoked by adduction.

Injury risk has been linked to decreased rotation at the hip and adductor/abductor imbalances (Järvinen et al., 1997; Mens et al., 2006a)

Tests:
Squeeze test (resisted adduction), hip muscle strength tests, Active straight leg raise test (ASLR), palpation, imaging (Tibor and Sekiya, 2008)

Osteitis Pubis

Pain arises from the symphysis pubis and can affect the scrotum, proximal adductors and rectus abdominis. Has been linked with instability and overload. Categorised into mechanical, obstetric, inflammatory and other causes. Can present with bone oedema. (Fricker, 1997; Fricker et al., 1991; Hölmich et al., 1999)

Tests:
Squeeze test, palpation of symphysis pubis, passive hip abduction, imaging (Thorborg, 2004; Tibor and Sekiya, 2008; Mens et al., 2006a)

Athletic Pubalgia/ Sportsman’s Hernia

Umbrella term which includes sportsman’s (inguinal) hernia, but overlaps with other labels. Involves the abdominal and pelvic muscles, and is caused by muscle imbalances related to uneven force distribution (exertional imbalance). Common in highly skilled footballers; due to the twisting and turning involved. (Rabe and Oliver, 2010; Weir et al., 2011)

Tests:
Palpation of adductor, symphyseal and abdominal sites, resisted sit up, resisted adduction, Valsalva manoeuvre, imaging (Larson, 2014; Hölmich et al., 1999)

Management

Individual differences are acknowledged. There is often an overlap in these presentations and hence similarities in the methods used to manage all of these conditions. Rest, modified loading, addressing deficits in range of movement, and rectifying muscular imbalances (through stretching, strengthening and motor control work) are used to progress the athlete to return to sport pain free. Passive modalities (including manual techniques, belts, injection and oral drug therapy) can be used but as active training programmes have shown themselves to be more effective, they are usually combined. Resistant conditions may be treated surgically, and shows a >80% return to sport. However compared to the conservative management of proximal adductor ruptures, surgery has shown significantly longer (p=0.001) periods of time before return to play (Schlegel et al., 2009; Choi and McCartney, 2008; Hölmich et al., 1999; Weir et al., 2011; Cusi, 2010;Ekçi and Beyzadeoglu, 2014)

Figure 1.4 An overview of common athletic pelvic / groin injuries, clinical tests and management strategies
1.6 Incidence of Pelvic / Groin Injuries in Sport

Determining the incidence of athletic pelvic / groin injury by specific conditions is not easily quantifiable. In view of diagnostic difficulties and overlapping presentations, diagnosis may be influenced by physician speciality (Harmon, 2007). However, it has been suggested that under a broad label, groin injuries represent between 12-16% of all injuries in football (Werner et al., 2009) and 5% of all sporting injuries (Hölmich et al., 1999). Football has been associated with a high incidence of groin injury along with ice hockey (Tyler et al., 2010), Gaelic Football (Glasgow et al., 2011), and American and Australian Rules Football (Verrall et al., 2014; Brophy et al., 2010). In terms of specific injuries football has been linked with a particularly high occurrence of athletic pubalgia (58%); a group of conditions regarded as being sport and position specific (Rabe and Oliver, 2010) and which appears to increase in incidence in more highly skilled players. This may be due to high frequency training providing more opportunity to over stress the ability of the pelvis to effectively transfer loads and reduce healing time. This type of mechanism has also been implicated in other injuries (see figure 1.4).

1.7 Athletic Pelvic / Groin Injury; A Multifactorial Problem

The mechanisms associated with athletic pelvic / groin are not entirely known (Ficek et al., 2008). Insight may be gained from looking at some of the factors that have been highlighted in relation to specific conditions, but is confounded by the overlap in presentations and condition labelling. However, as is evident in the following discussion, it is appropriate to consider that athletic pelvic / groin dysfunction is in many cases a multifactorial problem (Kinchington, 2012). An accurate diagnosis also needs to consider the sport and the techniques involved, as much as epidemiology (Fricker, 1997).
The following discussion identifies some of the mechanisms believed to be contributory factors in certain pelvic / groin conditions. Non-muscululoskeletal causes of pelvic / groin pain such as tumours, infection and gynecological conditions are also possible (Kanakaris et al., 2011) but are not within the remit of this thesis.

1.7.1 Trauma / Mechanical

One mechanism of injury that has been associated with groin injuries is the high speed manoeuvre which involves quick changes in travelling direction (Machotka et al., 2009). The high incidence of these injuries in sports like football, Australian Rules Football and ice hockey is reflected in the high speed twisting and turning manoeuvres which are common features of these sports. In general many of these acute injuries heal well after rest, but long-standing groin pain is still common (Jansen et al, 2008).

Other injuries such as SIJ dysfunction in athletes, defined as a failure in load transfer through the SIJ (Cusi, 2010), is often associated with high training loads (Prather, 2001). Osteitis pubis is considered to be a degenerative condition that affects the symphysis pubis and surrounding tissue, and is not always symptomatic (Jardí et al., 2014). This is another condition which may have a history of high work loads and repetitions (biomechanical overload)(Beatty, 2012), yet can also be linked with the high speed manoeuvres associated with adductor pain (Choi and McCartney, 2008). It has been suggested that this is due to overloading or loading failure that may be caused by numerous factors including insufficient warm up prior to sport and deficits and/or imbalances in flexibility, balance, fatigue, muscular control and strength, (Ficek et al., 2008).

Pregnancy is also an event which causes pelvic girdle pain (PGP) in up to 76.4% of women (Kanakaris et al., 2011). Peri partum and post partum PGP has been seen to influence elite female athletes as much as the non-athletic population (Bo and Backe-
Hansen, 2007), and confirm that pregnancy and childbirth are risk factors for subsequent conditions including low back and ongoing PGP.

1.7.2 Neuromuscular

Poor neuromuscular control and strength deficits have been implicated in pelvic and groin injury and are therefore felt to significantly influence successful rehabilitation (Ficek et al., 2008). Whether this causes dysfunction or if dysfunction leads to these deficits is not clear. Motor control deficits and imbalances have been cited in a range of conditions which put a rehabilitation focus on stability; low back pain (Hodges and Richardson, 1996), groin pain (Cowan et al., 2004), pelvic pain (Beales et al., 2010) and SIJ pain (Hungerford et al., 2003). Different types of groin injury have also been associated with neuromuscular deficiencies (Ekçi and Beyzadeoglu, 2014) including adductor injuries (Tyler, 2010) and athletic pubalgia (Rabe and Oliver, 2010). This may be attributed to an adductor/abdominal imbalance, and the across pelvis shearing forces that result from the pull of the stronger adductors (Mercouris, 2014). These shearing forces can be further exacerbated by factors including decreased range of movement at the hip (Harmon, 2007; Verrall et al., 2001), especially deficits in internal rotation. The latter results in inwards twisting which increases the stress over the symphysis pubis (Williams, 1978; Hackney, 2012).

1.7.3 Inflammatory

Many presentations (for example muscle strains) have a clearly defined inflammatory component, which are the result of a trauma. For others, however, this is less clear. Osteitis pubis, for example, has conflicting reports of having an inflammatory response; but this feature is not exclusive to all presentations (Prather, 2001).

Therefore, it is apparent that many of the mechanisms discussed may indeed not be condition specific, and may contribute to several diagnoses (Kinchington, 2012).
In summary, pelvic / groin injuries warrant attention due to their complex nature, chronicity, and their particularly high occurrence in sports such as football and ice hockey. There is still a lack of high quality evidence on the effectiveness of management techniques (Machotka et al., 2009; Serner et al., 2015), and the difficulties with diagnosis and management mean that athletic pelvic / groin injury may easily become a chronic source of pain (Brown et al., 1999; Ficek et al., 2008).

More research needs to be undertaken in this domain, in particular to clarify diagnostic criteria and evaluate the effectiveness of treatment modalities (Rabe and Oliver, 2010). Pain of a chronic nature becomes even more complex to understand. Although not within the scope of this thesis, it is acknowledged that this type of pain is associated with cortical and physiological changes, which influence the relationship between motor control and pain (Moseley, 2007). This strongly suggests that the management of chronic pain conditions require more than musculoskeletal rehabilitation; indicating a role for pain re-education.

1.8 Treatment of Athletic Pelvic / Groin Injury

Conservative management of exercise-related pelvic / groin injury is the norm (Almeida et al., 2013), but is not always successful (Fricker, 1997) because there lacks a gold standard approach, and symptoms in some individuals are resistant to improvement (Dojcinovic et al., 2012). This is evident from the discussion in section 1.3. Therefore a surgical approach is sometimes indicated in conditions including athletic pubalgia or “sports hernia” (Rabe and Oliver, 2010; Hackney, 1993; Larson, 2014); resulting in a return to sport in over 80% of cases. Although surgery provides a successful option for many individuals (Larson, 2014), it has been argued that surgery significantly delays the recovery time of these injuries (Rabe and Oliver, 2010). Surgical options depend on the
condition(s) and surgical technique involved; they will not be discussed in any more
detail because the focus of this work is supporting the physiotherapeutic management of
athletic pelvic / groin injury with dynamic orthoses.

1.8.1 Physiotherapeutic Approaches
A recent systematic review found that only 6% of studies on the management of athletic
groin injury were of high quality (Serner et al., 2015), with moderate evidence
supporting the use of exercise and multimodality approaches. Whilst exercise therapy
for athletic groin pain is commonly used, it has been found to require a treatment
duration of 3.8 to 16 weeks to be successful. This duration has a significant impact upon
a professional athlete and their team (Machotka et al., 2009). Fricker (1997) reiterates
the lengthy time involved in the healing of athletic groin injuries, highlighting osteitis
pubis as typically requiring on average 9.5 months of treatment in males (Fricker et al.,

Current physiotherapy management of sports-related pelvic / groin pain involves a wide
range of modalities. Early, acute stage management focuses upon the use of rest, ice,
and compression therapy (Ekçi and Beyzadeoglu, 2014). As healing occurs this
progresses to manual therapy (Quinn, 2010), optimal loading, strengthening exercises
(Fricke, 1997; Ficek et al., 2008), pelvic belt application and stabilisation exercises
(Lee, 2004). Re-training of muscular activation and timing are also used as part of the
transition to more functional athletic rehabilitation (Braun and Jenson, 2007). The
nature of this training has been influenced by the effects of pelvic / groin pain on the
function of local stabilisers (Cowan et al., 2004) and more global patterning (Kavcic et
al., 2004). There has also been increasing focus placed upon ensuring the optimal
function of kinetic chains as part of rehabilitation; addressing imbalances in the chain
which may have contributed to earlier injury (Ficek et al., 2008). However, the chronic
nature of many pelvic / groin injuries suggests that current management is not optimal.
In general the physiotherapeutic management of pelvic / groin pain is commonly supported medically with the use of anti-inflammatories, prolotherapy (Topol and Reeves, 2008; Topol et al., 2005) and locally administered anaesthetics and / or corticosteroids. However, with such a variety of different modalities, it is often difficult to measure the effectiveness of individual modalities, particularly when some conditions may be self-limiting (Braun and Jenson, 2007).

In terms of injury prevention, certain risk factors for injury are known and some can potentially be modified. Although a detailed discussion is not within the context of this thesis, risk factors which can inform injury prevention strategies include: limited range of motion at the hip (Ibrahim et al., 2007), previous injury of this nature, and muscle group imbalances (Harmon, 2007), particularly weak adductors (Engebretsen et al., 2010; Tyler et al., 2001). Therefore interventions to address instability and / or kinetic chain deficiencies are integral to both prevention and cure (Rabe and Oliver, 2010).

1.8.2 Pelvic Belts

Transverse pelvic belts (secured caudal to the anterior superior iliac spines) have been shown to decrease pain and improve function in both the post-partum population (Damen et al., 2002; Mens et al., 2001; Mens et al., 2006a), and in some athletes with pelvic / groin pain. In athletes it is a subgroup who demonstrate a positive ASLR and /or exhibit pain on the squeeze test who appear to respond well to a pelvic belt (Jansen et al., 2009; Jansen et al., 2010c; Mens et al., 2006a). Research has also shown that belts can decrease pain and improve the stability of the SIJ where laxity is associated with pain (Damen et al., 2002; Mens et al., 2006b). However, in pregnancy-related pelvic pain, it is asymmetric laxity at the SIJ that appears to be linked to pain, rather than laxity alone (Damen et al., 2001).
It has been shown that the application of 50 Newtons (N) of force has the most beneficial effect upon pain; with higher forces (up to 200 N) not showing any further benefits (Mens et al., 1999; Mens et al., 2006b; Damen et al., 2002). Despite being used in clinical practice and recommended by some authors (Ostgaard, 2007), the European Guidelines on Pelvic Girdle Pain state that pelvic belts cannot be formally recommended as a treatment strategy because of the lack of high quality research such as RCTs (Vleeming et al., 2008). However, a recent systematic review has concluded that there is moderate level evidence for external pelvic compression reducing pain and improving stability, and therefore should be explored as part of a multimodality management approach (Arumugam et al., 2012). This suggests that the effectiveness of pelvic belts warrants further but more robust research, and that other forms of external compression (including mechanical and manual) may also be appropriate.

Whilst the successful use of transverse belts has been reported (Mens et al., 2006a), including belts placed at the levels of the symphysis pubis, greater trochanters or SIJ, other directions of applied force have not been examined in the form of belts. This is a notable gap in the literature. Pelvic belts as a pelvic / groin pain management strategy will be examined in more detail because they offer an approach from which the following research builds upon.

1.9 Theory Behind Pelvic Belt Application

Belts are an example of external pelvic compression, and theorised to be able to influence force closure, form closure and motor control (Arumugam et al., 2012). Placement of a belt caudal to the ASIS is thought to imitate a contraction of TrA, whilst the action of the anterior pelvic floor is thought to be mimicked with the placement of a belt at the level of the symphysis pubis (Lee, 2004). In healthy participants research has
shown that a pelvic belt decreases activity in transverse and oblique muscles (Hu et al., 2010). However, SIJ pain patients who showed an improvement in ASLR performance with pelvic compression showed different responses; some demonstrated increased EMG activity whilst others demonstrated decreased EMG activity (Beales et al., 2010). It was theorised that these responses may classify patients as those lacking in force closure and motor control, and those lacking form closure. Findings from a review of literature on the effects of external pelvic compression on the lumbopelvic spine supports this notion (Arumugam et al., 2012). Beales et al. (2010) also showed that despite compression improving ASLR performance, the motor response strategies employed were still abnormal compared to healthy controls. This suggests the importance of neuromuscular re-education proposed by some authors (Lee and Vleeming, 1998; Panjabi, 1992b), and a multi-modality approach to rehabilitation.

The finding that there is a delay in TrA activation in participants with chronic groin pain (Cowan et al., 2004) suggests that there may be a link between altered motor control/force closure and pain, and it is possible that this may be addressed with the application of pelvic belts. However, the influences of other factors should also be considered, as some patient groups show improved symptoms with compression but still display abnormal motor responses (Beales et al., 2010), and belts have also been considered to improve form closure (Damen et al., 2002).

In addition to addressing form and force closure deficits (Snijders et al., 1998; Damen et al., 2002), it has also been theorised that belts may enhance proprioception (Jansen et al., 2010c; Sichting et al., 2014); possibly by stimulating cutaneous mechanoreceptors as has been discussed with compression shorts (Kraemer et al., 1998), unload muscles and ligaments (Pel et al., 2008), and act as a pseudo-fascia and compress musculature (Arumugam et al., 2012). It is also possible that pelvic / groin pain may be addressed
by an external force that rebalances any deficit by enhancing the muscle sling (s) role in the kinetic chain. The fascial links in these chains are believed to have a role in sensorimotor control and provide links to the active, passive and neural subsystems (Barker and Briggs, 2007).

Whilst transverse belts have been tested in different populations including athletes, and peri and post partum females, and are used clinically to manage pain and daily function (Vleeming et al., 2008), other belt configurations such as diagonal compression of the pelvic girdle have not been examined. Biomechanical work has indicated that position of a belt is more important than the load applied (Vleeming et al., 1992) and that the design of cause specific belts are warranted (Pel et al., 2008). Cause specific belts may be used in different positions (ASIS or greater trochanter) in order to modify SIJ compression and shear, or alter muscle activation levels, depending on what the patient requires to address the cause of their dysfunction. Therefore other belt configurations may offer an optimised approach to managing some types of athletic pelvic / groin pain. This is explored in chapter 3.

1.10 Orthoses

Rigid orthoses have played a significant role in supporting the management of musculoskeletal abnormalities (Morris, 2002). In more recent years there has been a move towards a lighter, flexible and more user-friendly style of orthoses. An example is dynamic elastomeric fabric orthoses (DEFOs); in this case elastomeric refers to Lycra®. DEFOs are now playing an increasing role as orthotic supports and are used to support the clinical management of a range of conditions including cerebral palsy, and muscular dystrophy (Rennie et al., 2000; Elliott et al., 2011; Gracies et al., 2000). They are
composed of elastomeric panels, which are selectively positioned by a therapist, in order to apply compressive forces which can be used in order to facilitate movements and/or positioning, whilst restricting undesirable movements or limb positioning. Their effect on pain has been suggested (Matthews et al., 2011), but has not been quantified. However, sports compression shorts made of similar materials to DEFOs, have been shown to significantly reduce post exercise pain \( p = <0.05 \) in athletes with osteitis pubis (McKim and Taunton, 2001). This was theorised as being the result of external pelvic compression limiting dysfunctional movement at the SIJ and symphysis pubis. Other findings suggest that this type of compression may also influence joint position sense (Kraemer et al., 1998); a mechanism that other authors have discussed in terms of belts (Jansen et al., 2010c) and lumbopelvic pain (Mens et al., 2001).

1.10.1 DEFO Development and Modification

The process of developing the DEFO (objective ii.) was informed by the results of the athletic pelvic belt study which directed the placement of applied force to the pelvic girdle (chapter 3). The resulting DEFO design was hand drawn and then created using Gerber Pattern Design Software, AccuMark Explorer and Made to Measure Software (Gerber Technology, Connecticut, USA). It was constructed from two different types of elastomeric fabric, a raschel fabric (polyamide 51%, dorlastan 32%, cotton 17%) and a power net fabric (polyamide 81%, elastane 19%). The former is used for the basic shorts pattern, whilst the power net, which is used in scar management compression garments (Macintyre and Baird, 2006), is strategically placed to deliver force. In this case power net panels were situated over the pelvic girdle (figure 4.1). Reduction factors (where a defined percentage is removed from pattern measurements) were also used to increase the level of compression where appropriate. This method is also used in scar management compression therapy (Macintyre, 2007).
The following information is derived from the manufacturer (DM Orthotics Ltd, Cornwall, UK), and explains the provision and use of a DEFO. As a DEFO is a bespoke orthosis and registered as a medical device (defined on the DEFO product labels), each athlete is required to be measured and fitted by a clinician. For the shorts eight individual measurements are taken around the pelvic girdle and thighs; both length and circumference. These measurements are used to generate a bespoke pattern. Following the fitting session, where position and fit are checked, athletes are advised to build up the wearing time from two hours to full daytime wearing (if full daytime wearing is desired) over a period of two weeks. In terms of contraindications, whilst there are few contraindications to wearing the shorts DEFO, the absence of these must be confirmed at the initial assessment. The contraindications to the shorts DEFO wear are: current pregnancy, open wounds, current or suspected fractures, compromised circulation and/or sensation and localised infection.

Following the development of the DEFO the single case studies provided a preliminary evaluation of the DEFO (chapter 4). It enabled durability aspects of the constructed pattern to be refined by adding extra material to the upper and inside of the thigh. It also enabled reducing the initial pelvic girdle reduction factor (used to deliver compression by reducing the size of parts of a pattern). This also led to the creation of male and female versions whose designs reflected anatomical differences, for example the male version has a larger space built into the crotch area. A design patent was subsequently attained (US D642,768 S) (Sawle et al., 2011).

In order to improve comfort, as indicated by questionnaire feedback from the pilot RCT (chapter 7), modifications to the leg seam construction were finalised in January 2015. This allowed the number of seams to be reduced, and improved the compression distribution between the pelvic girdle and upper thigh. Future modifications may look at fabric integrity and bonding seams, as technology is advancing in these areas. However,
no changes to the force configuration applied to the pelvic girdle (based upon the findings of chapter 3) have been made or will be made.

1.11 Conclusions

The literature has highlighted that athletic pelvic / groin pain is a multifactorial problem, which is diagnostically challenging and difficult to manage. The consequence of this is that there is a lack of quality evidence supporting effective management strategies, and a lack of consensus in the principles which should underpin rehabilitation.

The application of a transverse pelvic belt shows instantaneous improvements in pain and function with some patients (Mens et al., 2006a), whilst in other patients wearing a belt is no more effective than exercise (Depledge et al., 2005), or may have no effect (Jansen et al., 2009). It is plausible that other pelvic belt configurations may be of more benefit.

A DEFO may offer a more practical and bespoke tool for aiding the physiotherapeutic management of athletic pelvic / groin pain. The nature of the DEFO (as shorts) may allow force to be applied in directions which are difficult to sustain in belts, and are practical for a sporting setting.

The importance of physiotherapeutic management is also acknowledged as complementing the use of orthoses, and it is suggested that the DEFO be considered as part of a multi-modality approach to pelvic / groin pain. Exercise therapy is important to rehabilitation, as prolonged, active training programmes have demonstrated a 79% return to sport free pain rate compared to 14% following a standard physiotherapy programme (Hölmich et al., 1999). An appropriately designed DEFO may offer an
approach which contributes to principles associated with targeted exercise therapy i.e. strength, stability, and proprioception, and provide an adjunct to therapy.

1.12 Research

It was proposed that an athletic pelvic belt study looking at novel belt configurations would provide information regarding the direction of applied force to the pelvis in order to reduce pelvic / groin pain and optimize function. These results were used to inform the development of a customised athletic DEFO, which was subsequently evaluated in terms of its effect upon pain, clinical function and athletic performance. The investigation of these ‘new’ belt configurations provided further theoretical insights into how pelvic belts influence athletic pelvic / groin pain, and the opportunity to explore a novel adjunct to therapy.

1.12.1 Aims:

To explore the potential use of DEFOs in the management of athletic pelvic / groin pain

1.12.2 Objectives:

i. To examine the effects of various belt configurations upon pelvic / groin pain and function in athletes (Chapter 3)

ii. To use the results from the athletic pelvic belt study to inform the design of a customised DEFO (Chapters 4 and 7)

iii. To undertake a preliminary evaluation of the DEFO in terms of its effect upon pelvic / groin pain and function (Chapter 4)

iv. To identify potential performance effects and how these can be measured reliably (Chapters 5 and 6)
v. To conduct a pilot RCT examining the effect of this DEFO upon clinical and functional measures of performance, in order to inform a future definitively powered RCT (Chapter 7)

vi. To identify where further research is required (Chapter 8)

The structure of this thesis reflects the progression of work undertaken to develop a DEFO designed to support the management of athletic pelvic / groin pain, and explore its effectiveness and acceptability within this population.

The protocols used adopted standardized and validated clinical measures of pelvic / groin pain and function (chapter 2), whilst incorporating the findings of previous pelvic belt research.
2 Chapter Two Methods

The athletic pelvic belt study (chapter 3) and the single case series (chapter 4; with one modification on injury chronicity) employed the same patient eligibility criteria and outcome measures. The pilot RCT (chapter 7) also uses the same eligibility criteria with the addition of injury chronicity. This chapter presents these shared methods.

2.1 Eligibility Criteria

To participate in any of the studies, potential participants were asked to read study information sheets in order to understand what would be involved. This information was provided at least 24 hours before the screening session to give potential participants the opportunity to consider whether they would like to participate, and had any questions or concerns that they wanted to address before giving their informed consent.

At the start of the screening session participants were asked if they had read the information sheet(s), and if they had any questions. Before proceeding a brief overview of both the screening session and study procedures was verbally delivered by the investigator to the potential participants.

At the screening session the following was confirmed (verbally) for inclusion purposes:

i. Potential participants were engaged in sport / exercise, over 18 years old and able to give informed written consent

ii. Had a history of low to moderate (scored between one to seven on a numerical rating scale) pelvic / groin pain presenting during sport or at rest (Zelman et al, 2003). There was no time minimum or maximum on duration of pain, to allow for inclusion of both acute and chronic conditions.

Figure 2.1 shows the assessment process used to determine eligibility.
Subjective assessment:
Informed consent gained
Demographical data gathered
History of current and past pelvic/groin injuries (including self-reported site(s) of pain and management strategies used) recorded
Training undertaken for the last month collected

Extended subjective assessment:
Exclusion criteria questions including pain score (0-10), pregnancy, previous pelvic fracture, and co-morbidities. See exclusion criteria for full criteria

If YES answered to any question
Exclude and debrief

If NO answered to all exclusion questions

Objective assessment:
Observation and palpation to rule out exclusion criteria including acute fractures/ruptures/bursitis
Neuro screen conducted if indicated in the subjective assessment (myotomes, dermatomes, reflexes, passive straight leg raise).
Pain provocation tests (see 2.1.1 for details) undertaken

If screening met the inclusion and exclusion criteria then the participant was asked if they still wished to give their informed consent to partake in the study

Figure 2.1 The assessment process used to determine eligibility
2.1.1 Screening Procedure

To objectively confirm the presence of pelvic / groin pain, tests identified as appropriate in diagnosing pelvic / groin pain (Vleeming et al., 2008; Mens et al., 2006a; Stuber, 2007) were used as part of a battery. The tests were selected to confirm pain from the SIJ, symphysis pubis and adductor region; acknowledging that these are not mutually exclusive. These tests may be considered in terms of specific pelvic / groin conditions (figure 1.4) but as discussed throughout chapter 1 caution should be taken in concluding an exact diagnosis. The tests are presented in figures 2.1 to 2.5.

The battery of tests used were:

2.1.1.1 ASLR

This is a reliable measure of lumbopelvic load transfer which has been used with post-partum and athletic populations (Mens et al., 2001; Mens et al., 2006a). It has also been recommended as a functional test for those with pelvic pain (Vleeming et al., 2008). High sensitivity (0.87) and specificity (0.94) values have been reported for patients with post-partum posterior pelvic pain (Mens et al., 2001).

The procedure involves participants lying in supine on a plinth with their legs 20 cm apart, and being asked to raise their legs one at a time 20 cm above the plinth (Mens et al., 1999). The usual procedure involves participants scoring the difficulty that they have in completing the test; pelvic pain has been associated with significantly higher (p = <0.02) difficulty scores on this test (Palsson et al., 2014). For the purposes of screening participants were only asked whether the test evoked their pain. The presence
of the participant’s pelvic / groin pain was considered to be a positive response (figure 2.2).

2.1.1.2 **Patrick / Faber Test**

This test has been used to identify SIJ pain (as part of a battery of tests), but is also known to identify hip pathology (Byrd, 2007). In SIJ pain patients the sensitivity and specificity for this test ranges from 50% to 77%, and 16% and 100% respectively (Stuber, 2007).

This test is undertaken in a supine position whereby the participant’s leg is moved into flexion, abduction and external rotation, by placing one foot across the knee of their opposite leg. The therapist applies pressure to the externally rotated knee, and stabilises the opposite anterior superior iliac spine (Merriman and Turner, 2002). A positive test is determined if the participant’s pelvic / groin pain is provoked by pressure (figure 2.3).

2.1.1.3 **Bilateral Resisted Hip Adduction (Squeeze Test)**

This is a common test used to identify groin pain in athletes (Verrall et al., 2005), including but not exclusively adductor pain. It has been considered more appropriate to refer to pain elicited on this test as adduction related pain as structures other than the adductors can cause pain (Mens et al., 2006a).

Sensitivity and specificity for this test have been reported as 40% and 49%, and 88% and
91% respectively in athletes with groin pain (Verrall et al., 2005).

This test can be conducted in several different ways (section 2.2.1) but for the purposes of screening it was conducted with the participant lying supine on a plinth, hips at 45°, knees at 90° and feet flat on the plinth. Participants are asked to squeeze the therapist’s fist (placed between their knees) as hard as possible (Verrall et al., 2005). A positive test evokes the participant’s pelvic / groin pain (figure 2.4).

2.1.1.4 **Posterior Pelvic Pain Provocation Test (P4) or Thigh Thrust**

Laslett et al. (2005) identified this as the most sensitive test of SIJ pain, reporting sensitivity and specificity as 0.88 and 0.69 respectively.

The test is undertaken with the participant lying in supine, whilst the therapist flexes their knee and hip, before applying a downwards force through the knee towards the pelvis. A positive test is when the participant’s pelvic / groin pain is reproduced with the application of pressure (figure 2.5).

2.1.1.5 **Gaenslen’s**

This test has been recommended for use as part of a battery of tests for identifying SIJ pain, along with the Faber test and the thigh thrust (Vleeming et al., 2008). In SIJ pain patients sensitivity and specificity have been reported for the test performed on the right and left side.
as 0.53 and 0.71, and 0.50 and 0.77 respectively (Laslett et al., 2005).

To conduct the test the participant is asked to lie in a supine position. From this position, the therapist flexes the participant’s knee and hip whilst extending the opposite leg to lie off the plinth. Overpressure is applied to the flexed knee towards the pelvis, and downward pressure applied proximal to the knee of the abducted/extended leg. A positive test is determined if pain is provoked with pressure (figure 2.6).

For inclusion positive pain scores had to be determined on at least two of these five tests, as when used in isolation these tests are limited in terms of reliability, but when used together they provide a more reliable approach (Stuber, 2007).

2.1.2 Exclusion Criteria

The following exclusion criteria were used to exclude potential participants in order to ensure their safety, and to avoid confounding variables.

i. Anorexia - to exclude those with a risk of osteoporosis and thus having a pelvic fracture as their pain source

ii. Osteoporosis – to exclude risk of a pelvic fracture being responsible for pelvic / groin pain

iii. Sensory loss/weakness of neurological origin /neurological signs (determined by neurological examination) - which may influence pain perception, and will exclude the presence of lumbosacral radicular syndrome

iv. Current pregnancy or within six months post-partum

v. Co-morbidities-to exclude those with rheumatological, neurological, or systemic disease which may impact upon the outcome measures
vi. Suspected fracture based on clinical examination (e.g. Numerical rating scale [NRS] pain score >8/10, deformity, acute swelling, significant leg length discrepancy, and mechanism of injury)

vii. Trochanteric bursitis

viii. Muscle/tendon rupture

ix. Inguinal herniation

x. Previous pelvic fracture

xi. Severe pain (>8/10 on NRS). Excluded because repeated testing may exacerbate pain further

2.2 Outcome Measures

The following outcome measures were selected based upon their clinical appropriateness and situational relevance (measures that clinicians use in practice with athletes with pelvic / groin pain) and were standardised appropriately. They were used as portable tests.

The squeeze test and the ASLR are commonly used clinical tests, which have also been used in athletic pelvic / groin research (Mens et al., 2006a). As described below the ASLR was standardised so that each participant moved their leg through an identical arc, whilst the force produced on the squeeze test was measured objectively using a load cell, with knees in extension.

Pain at rest was selected to provide a baseline measure of each participant’s pain, whilst a broad jump was used as a functional measure relevant to athletes (field test of power). This was standardised to one metre.
Tests were always ordered as follows to minimise irritability: pain at rest, squeeze test, ASLR, and the broad jump.

2.2.1 Primary Outcome Measure

2.2.1.1 Squeeze Test Force

The squeeze test was selected as the primary outcome measure for reasons already mentioned (section 2.2), and because athletes with groin pain show decreased squeeze test force (Mens et al., 2006a). This suggests that this test is appropriate for measuring the deficits associated with this type of pain. It has shown excellent inter and intra tester reliability in athletes with and without groin pain (ICC ≥0.90; refer to chapter 6 for an explanation of ICCs and their interpretation) (Malliaras et al., 2009).

In clinic the squeeze test can be performed in several different positions, including hips at 0, 45 and 90 degrees of flexion; knees extended or knees flexed (Verrall et al., 2005; Glasgow et al., 2011). Clinicians can grade the strength of the muscle squeeze using a manual muscle test (MMT); where 0 = no flicker of a contraction and 5 = full strength against gravity and resistance) (Thorborg, 2012). Hölmich et al. (2004) introduced another grading method for manually assessing adduction strength as weak, intermediate and strong. Both measures are influenced by subjectivity.

In an attempt to make the test more objective, dynamometers (containing load cells) and sphygmanometers (blood pressure cuffs) have been used (Fulcher et al., 2010; Delahunt et al., 2011). Both methods have shown excellent inter and intra rater
reliability, but can be influenced by tester experience and test position. Hand held
dynamometry may also be influenced by the tester’s own strength (Thorborg, 2012).

For the purposes of this work a padded load cell was used so that the investigator’s
strength was not an issue. This method has been successfully used as an objective
means of measuring the squeeze test in athletes with and without a history of groin pain
(Lovell et al., 2012).

With participants lying in supine (hips at zero degrees), a padded load cell (SGA,
Applied Weighing, Reading, UK) was placed between the ankles at the level of the
medial malleoli. This position has been identified as the most appropriate for assessing
adductor related pain (Drew et al., 2015). Participants were asked to perform a bilateral
contraction of the hip adductors against the strain gauge and to continue the contraction
until they rated their pain as moderate (5/10 on a NRS) or they reached their maximum
contraction (Figure 2.7). Participants pressed a hand held switch to indicate this point.
The force at this point was measured via the load cell. Force and switch signals were
Analog to Digital (AD) converted at 200 Hz (Micro 1401, CED, Cambridge, UK) and
recorded using Spike2 software. The applied force at the point of the switch press was
directly measured via interactive cursors.

2.2.2 Secondary Outcome Measures

2.2.2.1 Pain on ASLR

The ASLR test is a functional test of load transfer through the pelvic girdle, whereby
patients self score the difficulty that they have in completing the test. Its test retest
reliability in post-partum posterior pelvic pain patients is excellent (ICC 0.87), and
although reliability values are not available for athletes the test has been used with
athletes with groin pain (Mens et al., 2001; Mens et al., 2006a; Jansen et al., 2009;
Jansen et al., 2010a,c).
The ASLR is undertaken on both legs and is scored from zero to five for each leg. A positive score is one or above (Mens et al., 1999). A significant positive and moderate relationship ($r = 0.53; p = 0.001$) has been shown between the difficulty score and the level of pain experienced (Palsson et al., 2014).

For the purposes of this work, the ASLR was used with self-reported pain scores. The NRS is considered a valid, and reliable tool for measuring pain. Compared to other scales it is the most responsive and sensitive (Williamson and Hoggart, 2005; Ferreira-Valente et al., 2011). Therefore as a measurement tool the ASLR can be seen as being able to detect when there is a clinically important change whilst remaining stable where is is no change (responsiveness), and, has the ability to correctly identify those patients who have difficulty in transferring load through the pelvic girdle (sensitivity). This test was used to measure the level of pain during the ASLR.

The test was undertaken with participants lying in supine before being asked to lift their leg (keeping their knee in extension) up to a bar placed 20 centimetres above the plinth and 65 cm distal to the greater trochanter to ensure all participants moved through an identical arc of 18° (Figure 2.2). Pain was measured by means of an 11 point NRS; where zero represents no pain and 10 is the worst imaginable pain. Both legs were tested one at a time, commencing with the right leg.
2.2.2.2 Pain at Rest

The participant was asked to lie in supine on the plinth (Figure 2.8). They were asked to rate the level of pain that they were currently experiencing using the 11 point NRS scale described in section 2.2.1.1.

Figure 2.8 Pain at rest

2.2.2.3 Standardised Broad Jump

The broad or standing long jump is an athletic field test used to measure power (Almuzaini and Fleck, 2008). This was selected in order to include a sports performance based outcome measure. In chapter 7 this test is discussed in detail within the context of its use as a field test of power in the the pilot RCT. In the studies described in chapters 3 and 4 this test was used in standardised format, whereby participants were asked to perform a standardised broad jump of one metre (figure 2.9). Distance was standardised to minimise pain irritability from repeated testing. Participants were asked to rate the pain that they were experiencing using the 11 point NRS immediately pre and post jump.

Figure 2.9 Standardised broad jump
3 Chapter Three Exploring the Effect of Pelvic Belt Configurations on Athletic Pelvic / Groin Pain

3.1 Introduction

Chapter 1 reviewed the approaches used to manage athletic pelvic / groin pain, and highlighted the use of transverse pelvic belts and the theory behind their application. These belts are usually placed just below the level of the ASIS, or at the level of the symphysis pubis or the greater trochanter (Mens et al., 2006a). To date, other pelvic belt and strap combinations have not been examined. Diagonal configurations which may provide a compression force towards or away from the site of pain warrant investigation based on the notion that they may provide an alternative method of belt application which is more effective than those currently used. It is possible that an asymmetry caused by pelvic / groin pain presenting on one side of the body, could be addressed by an external force that rebalances the asymmetry in force closure and/or joint mobility. This may support the actions of the muscle slings described by Lee (2001), as discussed in chapter 1.

The aim of this study was to establish if alternative applications of pelvic belts may decrease pelvic / groin pain and improve function in athletes. Improvements in pelvic / groin pain with particular directions of force application may inform the development of a DEFO.
3.2 Methods

3.2.1 Study Design

A repeated measures experimental design was used so that every participant could be tested under each condition and act as their own control.

3.2.2 Sample Size and Power Calculation

A sample of 20 athletes with clinically ascertained pelvic / groin pain, as determined by the screening procedure outlined in chapter 2, were recruited. Mens et al. (2006a) found a mean difference of 38 Newtons (standard deviation =13.8) in adduction force in athletes with groin pain with or without a pelvic belt. This resulted in an effect size of 2.7. Based on this effect size a sample size calculation was undertaken: for a + power of 0.99 and significance level of 5%, 11 participants were required in each group. However to accommodate variability in adduction force between those with left compared with right sided groin pain, the sample size was increased to 20 to minimise type II errors. The study was approved by the local ethics committee (Faculty of Health and Human Sciences Ethics Committee, Plymouth University; 01/2009) and people participated after informed written consent was obtained. Confirmation of ethical approval for this study and the other studies in this thesis can be found in appendix 1.

3.2.3 Eligibility Criteria

The inclusion and exclusion criteria are outlined in chapter 2.

3.2.4 Procedure

Instrumented pelvic belts and straps were constructed from 5cm white webbing, and consisted of a transverse pelvic belt (similar to that used in clinical practice) and additional pelvic straps to traverse across the pelvis (right to left, and left to right). Additional straps were employed to allow the diagonally orientated belts to be secured
around the upper thigh (see figure 3.1). This method was used to ensure that the belts remained in place during testing. A low profile load cell (S250, SMDsensors, Bury St Edmonds, UK) connected to an amplifier was (Applied Weighing, Reading, UK) calibrated using 5 x 1 kilogram (Kg) weights. These were attached in series to the load cell and the voltage increase per Newton of applied force calculated. The load cells were used to determine the applied force of 50N. In each belt signals from the load cell were AD converted (200Hz, micro1401, CED, Cambridge, UK) and displayed (SPIKE2 software, CED, UK) to allow consistency of load application across participants. Figure 3.1 shows the pelvic belt configurations.

Figure 3.1 The pelvic belts with the load cells in situ
Following the screening process, data pertaining to injury, training and demographics were gathered. The outcome measures (chapter 2) were then undertaken in a standardised order across each of the five belt conditions; see below. The measures were ordered to minimise irritation from undertaking each test, and standardised to be consistent across all participants. The order in which participants were tested under each of the belt conditions was randomised using codes generated using the randomisation function in Microsoft Excel. This randomisation was to minimise the influence of order and sequence effects (McBurney and White, 2009). Conditions were:

1. No belt
2. A belt just below the ASIS (Mens et al., 2006a)
3. A belt traversing right to left diagonally across the pelvis
4. A belt traversing left to right diagonally across the pelvis
5. A combination of right and left diagonal belts

Each of these positions (except no belt) was tested with an applied force of 50N; checked using a voltage meter attached to the output of the load cell amplifier. Each belt was worn for five minutes; this reflects the time taken to complete all of the outcome measures.

Standardised instructions were given to each participant to ensure accuracy of the information given and to control for confounding variables such as verbal motivational cues delivered by the investigator (Searle, 1999). A standardised ‘flush out’ period of three minutes between each intervention was used to avoid carryover effects, and to minimise irritation of the injury (Damen et al., 2002). This involved a rest period, where the participant was asked to lie in supine on the plinth. The relatively short duration of
rest was accounted for by ordering the tests from least to most irritable, and excluding those athletes with a high pain score (≥8/10; explained in chapter 2).

3.2.5 Outcome Measures

3.2.5.1 Participant Training and Injury Data

A standardised questionnaire was used to gather demographic data, details relating to the training regime (frequency and type of training), injury and pain history, and sport specific information.

The outcome measures were undertaken for all conditions, as described in chapter 2. The measures selected were chosen on the premise that they are tests used clinically and/or in the field, and in the cases of the ASLR and squeeze test, are used in pelvic belt related research (Mens et al., 2006a; Jansen et al., 2009; Jansen et al., 2010a,c).

3.2.5.2 Tests

See chapter 2.2 for details on the following:

1) Pain at rest while lying in supine
2) Pain during ASLR
3) Force produced on the squeeze test
4) Standardised Broad Jump

As this was a repeated measures design participants undertook each of the outcome measures five times; once for each condition.

3.3 Analysis

Statistical analyses were performed using SPSS 19 for Windows. The control and each experimental condition were compared using a repeated measures ANOVA (five
factors; the no belt control and belt positions two to five). The latter was selected as the assumptions for using a parametric test were met. A greenhouse geisser correction was applied if assumptions of sphericity were violated. A priori contrasts were used to explore whether there was any difference between the no belt condition and the four belt configurations. Significance level was selected at $P \leq 0.05$.

For purposes of analysis and to correspond to clinical terminology, the right to left and left to right belt configurations were re-labelled ipsilateral to contralateral, and contralateral to ipsilateral, relative to each participant’s site of pain.

3.4 Results

3.4.1 Demographics

Twenty-two athletes from various sports / physical backgrounds and with pelvic / groin pain were assessed. After screening, 20 were eligible for inclusion (14 female) and provided written informed consent to partake in the testing process. Table 3.1 provides details of their demographic characteristics. There was a mixture of both chronic (more than 12 weeks duration $n=15$) and acute (less than 12 weeks duration $n=5$) conditions, and locations of pain with some participants reporting more than one site of pain. Sports included Rugby Football Union (rugby), Association Football (football), power walking, boxing, beach sprints, squash, running and cycling. Many participants reported being involved in several sports. All participants were training between three and five times per week undertaking a mixture of aerobic and anaerobic training. Nineteen of the participants were recreational level athletes (two of whom had previous experience of national level sport), and one athlete was competing at international level.

Table 3.2 presents the pain location, history, and responses to the pain provocation tests used in the screening process.
<table>
<thead>
<tr>
<th></th>
<th>Height in Metres</th>
<th>Weight in Kilograms</th>
<th>Age in Years</th>
</tr>
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<tr>
<td><strong>Mean</strong></td>
<td>1.70</td>
<td>72.6</td>
<td>34.6</td>
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<tr>
<td><strong>SD</strong></td>
<td>0.09</td>
<td>15.4</td>
<td>9.8</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>1.53-1.86</td>
<td>39.5-94.9</td>
<td>20-62</td>
</tr>
</tbody>
</table>

Table 3.1 Participant demographics
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</tr>
</thead>
<tbody>
<tr>
<td>Participant Number</td>
<td>Sport(s)</td>
<td>Site(s) of injury</td>
<td>Mechanism</td>
<td>Nature</td>
<td>Squeeze Test</td>
<td>ASLR</td>
<td>Faber’s Thrust</td>
<td>Gaenslen’s Thrust</td>
</tr>
<tr>
<td>1</td>
<td>Gym, sailing, canoeing</td>
<td>Posterior pelvis, unilateral (L)</td>
<td>Trauma</td>
<td>Chronic</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>Jogging, cycling, rugby union</td>
<td>Posterior pelvis, unilateral (L)</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>Pilates, walking, swimming</td>
<td>Anterior, posterior pelvis. Bilateral groin</td>
<td>Pregnancy</td>
<td>Chronic</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Football, cycling, running</td>
<td>Bilateral groin</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
<td>Problem Location</td>
<td>Etiology</td>
<td>Condition</td>
<td>Acute</td>
<td>Chronic</td>
<td>Cause</td>
<td>Result</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>5</td>
<td>Rugby union, weights, cardio-vascular training</td>
<td>Anterior pelvis, groin muscles (L)</td>
<td>Unknown</td>
<td>Chronic</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>Football, squash, running</td>
<td>Groin (R)</td>
<td>Trauma</td>
<td>Acute</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>Jogging, cycling</td>
<td>Posterior pelvis, unilateral (L)</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Power walking</td>
<td>Bilateral posterior pelvis, unilateral groin (L)</td>
<td>Overuse</td>
<td>Acute</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>9</td>
<td>Swimming, walking, cycling, running</td>
<td>Posterior pelvis, unilateral</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
<td>Location</td>
<td>Injury Type</td>
<td>Acute</td>
<td>Chronic</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>---</td>
<td>----------------------------------</td>
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</tr>
<tr>
<td>10</td>
<td>Badminton, squash, gym work, walking</td>
<td>Posterior, anterior pelvis (R)</td>
<td>Overuse</td>
<td>Chronic</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>11</td>
<td>Strength training, boxing training</td>
<td>Anterior, unilateral (R)</td>
<td>Cutting</td>
<td>Acute</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>Running, walking, aerobic exercise</td>
<td>Posterior, bilateral pelvis</td>
<td>Overuse</td>
<td>Acute</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>13</td>
<td>Yoga, aerobics</td>
<td>Posterior, bilateral pelvis</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>14</td>
<td>Swimming, walking</td>
<td>Posterior, bilateral pelvis</td>
<td>Trauma</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
<td>Location</td>
<td>Injury Type</td>
<td>Acute</td>
<td>Chronic</td>
<td>Overuse</td>
<td>Trauma</td>
<td>Yes</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------</td>
<td>---------------------------</td>
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<td>-------</td>
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</tr>
<tr>
<td>15</td>
<td>Power walking, strength work</td>
<td>Posterior, central pelvis</td>
<td>Overuse</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>16</td>
<td>Fitness training, athletics</td>
<td>Anterior, posterior, bilateral pelvis (more R)</td>
<td>Overuse</td>
<td>Chronic</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>17</td>
<td>Football</td>
<td>Anterior, posterior, central pelvis</td>
<td>Overuse</td>
<td>Chronic</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>18</td>
<td>Surf life saving</td>
<td>Anterior, bilateral groin</td>
<td>Overuse</td>
<td>Chronic</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>19</td>
<td>Boxing training, gym</td>
<td>Posterior, anterior, central pelvis</td>
<td>Trauma</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
### Table 3.2 Self-reported injury history and participant responses to pain provocation tests.

2/5 positive tests are required for inclusion. Positive and negative responses to pain are denoted by + and – respectively. ASLR = active straight leg raise test. SIJ = sacroiliac joint. L = left. R = right

<table>
<thead>
<tr>
<th>Patient</th>
<th>Exercise Type</th>
<th>Injury Location</th>
<th>Injury Type</th>
<th>Chronic Status</th>
<th>Test Response 1</th>
<th>Test Response 2</th>
<th>Test Response 3</th>
<th>Test Response 4</th>
<th>Test Response 5</th>
<th>Inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Running, aerobic exercise</td>
<td>Anterior, bilateral pelvis</td>
<td>Overuse</td>
<td>Chronic</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>21</td>
<td>Gym, badminton</td>
<td>Anterior, bilateral pelvis</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>Yes</td>
</tr>
<tr>
<td>22</td>
<td>Running</td>
<td>Posterior, bilateral pelvis</td>
<td>Overuse</td>
<td>Chronic</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Yes</td>
</tr>
<tr>
<td>Belt Condition</td>
<td>Squeeze Test Force (N)</td>
<td>Pain at Rest (NRS)</td>
<td>Ipsilateral ASLR (NRS)</td>
<td>Contralateral ASLR (NRS)</td>
<td>Change in Pain on Broad Jump (NRS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------</td>
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<td>-----------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Belt</td>
<td>98.5 ± 33.6</td>
<td>0.8 ±1.1</td>
<td>1.4 ±1.6</td>
<td>0.8 ± 1.3</td>
<td>0.2 ± 1.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASIS</td>
<td>108.2 ± 37.4</td>
<td>0.5 ±1.1</td>
<td>1.2 ±1.5</td>
<td>1.1 ± 1.4</td>
<td>0.4 ± 1.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ipsilateral to</td>
<td>101.3 ± 38.9</td>
<td>0.6 ±1.2</td>
<td>1.1 ±1.7</td>
<td>1.0 ± 1.3</td>
<td>0.3 ± 1.9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contralateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contralateral to</td>
<td>106.0 ± 36.1</td>
<td>0.5 ±1.1</td>
<td>1.0 ±1.6</td>
<td>0.8 ± 1.2</td>
<td>0.3 ± 0.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ipsilateral</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>101.5 ± 37.8</td>
<td>0.5 ±1.1</td>
<td>0.9 ±1.4</td>
<td>0.6 ± 1.2</td>
<td>0.1 ± 1.1</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Table 3.3 Effects of pelvic belt configuration on applied force and pain.

Mean ± standard deviation is indicated. Ipsilateral-contralateral refers to a belt traversing from the side of pain to the opposite side of the pelvis. Contralateral-ipsilateral refers to the opposite. N =Newtons, NRS = Numerical Rating Scale.
3.4.2 Outcome Measures

Force produced on the squeeze test showed a significant effect of condition (F (4, 76) =2.7 P<0.05). Within participants contrasts demonstrated that the force produced was significantly lower in the “no belt” condition compared to the ASIS condition (ASIS F (1, 19) =9.3 P<0.01), and a belt traversing towards the site of pain (contralateral to ipsilateral, F (1, 19) =5.2 P<0.05, table 3.3).

For the ipsilateral ASLR there was a tendency for the pain to decrease across conditions (F (4, 76) =2.5 P = 0.05). Contrasts revealed that there was a significant reduction in pain in the contralateral to ipsilateral (F (1, 19) =8.2 P<0.01) and “combined belts” conditions (F (1, 19) =8.6 P<0.01) compared to the “no belt” condition (table 3.3).

There was no effect of belt condition on resting pain (F(4,76)=1.9  P>0.05), contralateral ASLR (F(4,76)=2.2  P>0.05) or the change in pain levels from undertaking a broad jump (F(4,76)=0.34  P>0.05).

3.5 Discussion

Pelvic belts providing compression towards the site of pain produced a decrease in pain experienced during the ipsilateral ASLR. The ASIS belt produced an improvement in ability to self-generate adduction force and the combined diagonal belts produced an improvement in ASLR-related pain, compared to “no belt.” The improvement in pain and function may be caused by the belts enhancing force or form closure; Damen et al. (2002) found SIJ laxity decreased with pelvic belt application. Other mechanisms are however also possible, since not all pelvic / groin dysfunction is associated with form / force closure deficits (Mens et al., 2001). For example activation of muscles such as transversus abdominis, that are felt to play an important role in force closure, have demonstrated significantly less resting thickness in
longstanding pelvic / groin pain patients (Jansen et al., 2010a), and delayed activation levels have been seen in both low back pain patients (Hodges and Richardson, 1996) and groin pain patients (Cowan et al., 2004). However, more recent work has shown that there is no abdominal feed forward delay in chronic low back pain patients, as measured by Doppler imaging (Gubler et al., 2010). Further changes in muscle thickness or activation pattern following resolution of pain with rehabilitation is not always apparent (Jansen et al., 2009), suggesting that other mechanisms may also have an impact.

Mens et al. (2001) discussed the influence of disturbed proprioceptive in relation to lumbopelvic pain, and how this may offer another explanation for the occurrence of this type of pain and/or dysfunction. Alterations in proprioceptive responses may be linked to deficiencies in muscle function, and propagated by factors such as fatigue and pain. Decreased proprioceptive acuity has been linked to poor movement control (Luomajoki and Moseley, 2011). Other work has suggested that pelvic belts may provide an improvement in hip muscle proprioception (Jansen, 2010c). Improved proprioception has also been reported in the trunk and limb following neoprene bracing (McNair and Heine, 1999; Birmingham et al., 1998) and hypothesised to underlie some of the actions of taping (Robbins et al., 1995). Therefore belts may have an influence upon proprioception.

In the current study, the fact that many athletes engaged in multiple sports and had variable sites and causes of pain may also have influenced the mechanisms underlying any clinical effect. As discussed throughout chapter 1 this type of presentation is not uncommon, but makes understanding the exact dysfunction and mechanisms behind their response to pelvic compression difficult to ascertain.

It is acknowledged that any improvement in pain and function may have been the result of belts addressing the symptoms rather than the cause of dysfunction. This was the
finding of Beales et al. (2010) who found that manual compression improved ASLR performance in SIJ pain patients, but that muscle responses remained abnormal. In this respect, whilst any symptoms of instability may be resolved with the use of a belt, the cause of any instability (for example muscle weakness or proprioceptive deficit) may not be. Addressing causes of dysfunction supports the notion of using a multi-modality approach to managing pelvic / groin pain. For some patients this may mean using a form of external pelvic compression (manual, belt or DEFO) to manage pain alongside the use of a directed exercise programme (Hölmich et al., 1999) to focus upon more efficient motor control. More work is needed to explore the appropriate use of external pelvic compression, and its mechanisms.

3.5.1 Limitations

The selection of outcome measures encompassed tests used both within the clinical (ASLR and squeeze test) and sports arena (broad jump). What became apparent during the testing process was that these tests were often not reproducing the athletes’ pain. From an ethical perspective minimising irritability with repeated measurement in one session was essential. Some athletes, who did not experience any pain during testing (possibly because of the lack of stressful tests), were still able to clearly identify sporting activities that exacerbated their pain tremendously, for example pain during ‘cutting’ manoeuvres (Cowan et al., 2004). A consideration for further research may be to incorporate more stressful tests that may be able to recreate the stress placed upon the pelvis during sporting activities, while also ensuring that the testing procedure provides adequate recovery time to minimise irritability. One potential measure is a variation on the bilateral adduction test; patient’s knees in extension, and the hips raised to 30 degrees of flexion with 10 degrees internal rotation, while adducting against resistance (Verrall et al., 2005). This is often used to test adductor and / or osteitis pubis pain in athletic populations, alongside the tests used in this study, but is more stressful. Other
test positions also need considering such as placing the padded load cell between the medial femoral condyles with the knees in extension (Hanna et al., 2010).

Whilst the results do appear to be in line with suggestions from the limited pelvic belt literature (Mens et al., 2006a; Jansen et al., 2009), inclusion of more stressful tests of pelvic / groin pain may enable differentiation between the ASIS and diagonal belt configurations in their ability to improve function and reduce pain.

### 3.6 Conclusions

The results support previous studies demonstrating that a transverse belt placed just below the level of the ASIS improves pain and squeeze test force (Mens et al., 2006a). The results further suggest that the application of diagonal forces towards the site of pelvic / groin pain, and delivering bilateral diagonal pelvic compression, may have additional benefits in improving pain and function compared to no belt or a transverse belt.

This information was used to inform the development of a DEFO (in the form of shorts); chapter 4. In chapter 4 a preliminary evaluation of the DEFO was undertaken by way of a case series involving athletes with pelvic / groin pain.
Chapter Four Evaluating a Dynamic Elastomeric Fabric Orthosis (DEFO) Developed to Aid the Management of Athletic Pelvic / Groin Pain

4.1 Introduction

Chapter 1 outlined discussed athletic pelvic / groin injury and the difficulties in its management related to the common occurrence of more than one site of injury, issues with accurate assessment, and the low quality of evidence supporting current modalities (Ficek et al., 2008; Serner et al., 2015). The use of pelvic belts was also discussed in terms of their strengths and limitations. It was suggested that a DEFO may offer a novel way of delivering targeted compression, replicating the action of pelvic belts in a more dynamic form.

In chapter 3 belt arrays were used to investigate the application of transverse and diagonally orientated forces to the pelvic girdle, and their effect upon athletic pelvic / groin pain and function. The results suggested that the application of diagonal forces towards the site of pain may have additional benefits in improving pain and function compared to no belt and a transverse belt (Sawle et al., 2013). These results subsequently informed the development of a DEFO designed to aid in the management of pelvic / groin pain in athletes.

The aim of the following study was to employ a series of case studies to explore whether the effectiveness of transverse and diagonal pelvic belts for athletes with pelvic and/or groin injury highlighted in chapter 3 can be replicated by a purposely designed DEFO. Whilst single case study designs are considered useful in undertaking an initial evaluation of clinical interventions (Morgan and Morgan, 2009; Dallery et al., 2013), the intention was to follow up any preliminary findings with a pilot RCT.
It was hypothesised that athletes with pelvic or groin injury may experience improvements in pain and/or function when wearing the DEFO. The same outcome measures as were implemented in the original pelvic belt study were used to enhance comparability between the studies. These were detailed in chapter 2.

4.2 Methods
4.2.1 Study Design
An AB case series study design (Kazdin, 1984) was used with a randomised onset of intervention (Morgan and Morgan, 2009). Randomisation was employed to strengthen the internal validity of the design (Kratochwill and Levin, 2010); thus helping to establish cause and effect and greater scientific credibility. This approach also allows the use of randomisation tests.

4.2.2 Sample
A mixed sex sample of athletes with clinically ascertained pelvic / groin pain, as determined by the screening procedure outlined in chapter 2, were recruited. Eight participants were recruited (two males), thereby enabling the additional group analysis termed randomisation testing (Todman, 2002). Randomisation tests are discussed in section 4.3. Eight participants is considered to be an appropriate number for this type of design (Dallery et al., 2013).

4.2.3 Intervention
The study was approved by the local ethics committee (Faculty of Health and Human Sciences Ethics Committee, Plymouth University; 03/2009) and people participated after informed, written consent was obtained.
4.2.4 Eligibility Criteria

Eligibility criteria are outlined in chapter 2. Due to the length of the study (three weeks of daily testing plus a follow up session after one month) the inclusion criteria was modified to recruit participants with longstanding pelvic / groin pain. In line with Jansen et al., (2009) longstanding pain is defined as lasting for four weeks or more.

4.2.5 Procedures

To minimise threats to internal validity continuous assessments (in this case daily test sessions) were performed (Kazdin, 1981), and randomisation was integrated into the design. Fifteen daily testing sessions were undertaken, with at least six test sessions during each phase (baseline and intervention). Figure 4.1 presents a flow chart outlining the order and structure of the testing sessions.
Figure 4.1 Shows the structure and ordering of the testing sessions
In the baseline phase athletes wore loose fitting sports shorts for the testing sessions to standardise what was worn and to prevent confounding effects from the use of other elastomeric fabric shorts (these were provided).

The intervention phase started on either day seven, eight or nine; the order of onset being randomised using random numbers generated via the randomisation function in Microsoft Excel 2010.

During the intervention phase participants wore the DEFO (figure 4.2) during testing and for activities of their choice. Participants wore their DEFO for periods of time that they felt were appropriate for their needs. The latter was recorded via a training diary, which was to provide information on how participants differed in how they used the DEFO in different settings.

Outcome measures were: the squeeze test with force measured via a load cell, self-reported pain (NRS) at rest and during the squeeze test, an ASLR, and a broad jump. Refer to chapter 2 for a full explanation of these measures.

In each phase (baseline and intervention) the outcome measures were repeated twice, and separated by a 10 minute rest in order to minimise irritability and to allow change of shorts into/out of the DEFO as required. At baseline regular sport shorts (non Lycra®) were worn during both test sessions; during the intervention phase participants first wore the DEFO and then the ordinary shorts. This procedure was employed to examine any carryover from wearing the DEFO; that is whether there were any changes without the DEFO in situ that may be linked to its prior use. Other studies have confirmed a carryover effect of DEFOs in neurological populations (Matthews et al., 2009). At one month post the initial testing period, participants were retested as for the intervention phase, and completed a questionnaire regarding their DEFO usage (appendix 2). This bespoke questionnaire was developed to record the athlete’s
subjective experiences of the DEFO alongside the standard outcome measures (Boynton and Greenhalgh, 2004), with the intention of using it in future studies.

4.2.5.1 The DEFO

The DEFO is presented in figure 4.2 and was designed to deliver a compressive force to both the anterior and posterior aspects of the pelvic girdle via Lycra® reinforcement panels. A diagonal panel configuration lies over the symphysis pubis, whilst over the SIJ there is a transverse panel. The DEFO was designed in this way to encompass a range of pelvic / groin conditions, particularly as the literature has discussed the common occurrence of more than one site of injury (Ficek et al., 2008), and the common existence of bilateral pain (Mens et al., 2006a). The diagonal panel was informed in part by the results of the athletic pelvic belt study, whilst the transverse panel represents the role that transverse belts have been found to play in pelvic / groin pain management (chapter 3).

Figure 4.2 The DEFO

This shows the placement of anterior (diagonal) and posterior (transverse) panels
4.3 Analyses

Visual analysis of trend, level and slope was undertaken on all data (Wolery and Harris, 1982). Mean (+/- 2 SD) (Reza Nourbakhsh and Ottenbacher, 1994) was plotted for the force data and pain scores, followed by celeration lines (Hojem and Ottenbacher, 1988; Reza Nourbakhsh and Ottenbacher, 1994) and calculation of the point of non-overlapping data (PND) statistic (Kazdin, 1984) where appropriate. The celeration line is obtained by plotting the baseline data and using the equation from the trend line (calculated using a least squares error method) to predict the continuation of this data. Reza Nourbakhsh and Ottenbacher (1994) detail the steps involved in the latter, as well as the two-standard deviation band. For both the +/- 2SD method and the celeration line, results were interpreted as being significant if there were at least two consecutive scores above or below the respective lines during the intervention phase. For an improvement in force to be significant, two consecutive scores would be above the mean +2SD and celeration lines; for pain scores to show a significant improvement the two consecutive scores would be below the mean -2SD and celeration lines.

The PND statistic indicates treatment effectiveness; comparing overlapping data in the baseline phase to the intervention phase. Scores >70 % are deemed effective treatment, with 50 to 70% considered questionably effective (Scruggs and Mastropieri, 1994). The use of these statistical tests in addition to the visual analysis, enables consistent results (not dependent upon who is analysing the results) and furthermore stable baselines are not essential (Reza Nourbakhsh and Ottenbacher, 1994).

4.3.1 Randomisation Tests

AB multiple baseline randomisation tests (Todman and Dugard, 2001) were undertaken using MatLab (MathWorks, UK) for each of the outcome measures (with and without the DEFO). This enabled the data from all of the single case studies to be combined as a group, and examined to see whether any improvement in pain and/or function was due
to the intervention or chance. This method works on the principle of comparing the change in an outcome measure between the baseline and intervention phase across all participants. As the onset of the intervention phase was randomised between the eight participants, it is possible to compare the actual change in the score with the change in the score if the onset had occurred at one of the other possible intervention points. In this case intervention could occur at three possible points (day seven, eight or nine) and eight single case studies were performed. This resulted in a potential 6561 possible combinations or $3^8$. The MatLab program randomly generated 2000 combinations i.e. that could start on day seven to nine for participant one to eight. In each case the difference between the mean of these randomly defined “baseline” and “intervention” phases were calculated. The percentage of randomly generated change scores that were lower than that actually recorded provides a probability that the actual change did not occur by chance. If their actual change was higher than all the randomly generated change scores this resulted in a probability of 0.0005 (i.e. 1 in 2000 comparisons). Significance level was set at 0.05. Therefore, if more than 100 randomly generated change scores were higher than that actually achieved then the probability that this occurred by chance is $>0.05$ and considered to be non-significant.

### 4.4 Results

Participant details are summarised in table 4.1.
<table>
<thead>
<tr>
<th>Case Study</th>
<th>Gender</th>
<th>Sport</th>
<th>Age (Years)</th>
<th>Height (Metres)</th>
<th>Weight (Kilograms)</th>
<th>Site of Pain</th>
<th>Duration of Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>Football, running, cycling, squash</td>
<td>37</td>
<td>1.86</td>
<td>73</td>
<td>Adductor</td>
<td>3 months</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>Rugby, running, cycling</td>
<td>31</td>
<td>1.81</td>
<td>84.4</td>
<td>SIJ</td>
<td>3-4 years</td>
</tr>
<tr>
<td>3</td>
<td>Female</td>
<td>Power walking</td>
<td>62</td>
<td>1.67</td>
<td>63.4</td>
<td>Adductor and SIJ</td>
<td>6 months</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>Yoga, aerobic/ power training programmes</td>
<td>29</td>
<td>1.72</td>
<td>87.5</td>
<td>SIJ</td>
<td>3 years; worse in the last 18months</td>
</tr>
<tr>
<td>5</td>
<td>Female</td>
<td>Boxing training</td>
<td>53</td>
<td>1.53</td>
<td>39.4</td>
<td>SIJ</td>
<td>2 years</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>Aerobic/ power training programmes</td>
<td>26</td>
<td>1.65</td>
<td>58.1</td>
<td>SIJ</td>
<td>2 years</td>
</tr>
<tr>
<td>7</td>
<td>Female</td>
<td>Skiing</td>
<td>42</td>
<td>1.60</td>
<td>68.2</td>
<td>SIJ</td>
<td>17 years</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>Cycling, swimming</td>
<td>34</td>
<td>1.68</td>
<td>54</td>
<td>SIJ</td>
<td>20 years</td>
</tr>
<tr>
<td>-----</td>
<td>--------</td>
<td>-------------------</td>
<td>----</td>
<td>------</td>
<td>----</td>
<td>-----</td>
<td>----------</td>
</tr>
</tbody>
</table>

**Table 4.1 Demographic information**
The results for each participant are presented below. Each case study is separately described using figures for the DEFO (left hand side) and control shorts (right hand side) for each of the outcome measures. FU refers to the follow up testing session (four weeks after the intervention phase). A legend is provided at the start of the first case study’s figures to explain the labels used.

An overview of the participant presentation is given along with a summary of their results, and the results of all studies are summarised in table 4.2 along with PND statistics. The case study effects when wearing the DEFO are summarised in table 4.3.

A group analysis was also conducted using a randomisation test.
4.4.1 Single Case Study One (Figures 4.3 A-N)

This participant was a 37 year old male who presented with unilateral adductor pain, aggravated by adduction based activities. His sports were football, running, cycling and squash. He exercised on a daily basis.

Due to fluctuating pain scores this participant’s baseline phase was extended to 11 days in an attempt to gain a stable baseline. Therefore the subsequent intervention phase was also extended to 11 days.

Figures 4.3 A and B demonstrate a significant improvement (according to mean +2SD and celeration line) upon force output in the squeeze test during the intervention phase. Figure 4.3 B suggests that there may be a carryover effect in the second assessment due to wearing the DEFO in the first assessment. The PND statistic (58.3 %) suggests that the DEFO was a questionably effective treatment.

Pain scores (figures 4.3 C-N) demonstrate a significant reduction in pain as assessed by the celeration line values. Although none of the pain related outcome measures were significant according to the mean -2SD method or PND statistics, pain levels are more stable when the DEFO is worn compared to baseline, and this is a factor which may have clinical importance to an athlete. It also showed that this effect was carried over to wearing control shorts in the intervention phase.

The follow up session shows that force output remained significantly improved for both the DEFO and control shorts. Pain on the squeeze test was seen to drop significantly (below the mean -2SD) for both the DEFO and control shorts, suggesting that wearing the DEFO over the preceding month may have contributed to this decrease. However, it is also possible that this was the result of his condition improving through natural recovery.
Figure 4.3 Figures for case study one
4.4.2 **Single Case Study Two** (Figures 4.4 A-N)

This participant was a 31 year old male who presented with SIJ pain which was aggravated by repeated bending and rugby. His sports were running, cycling and rugby. He exercised on a daily basis.

When wearing the DEFO he showed pain scores (for all outcome measures) which were consistently below the celeration lines, indicating that his pain decreased with DEFO usage. This was not confirmed by the mean -2SD method; however the PND statistic for the level of pain post broad jump indicated effective treatment (75%). The effects shown when wearing the DEFO are similar for when control shorts were worn during the intervention in all measures except pain on the squeeze test. Figure 4.4 D shows that pain levels are more variable when control shorts are worn.

In terms of squeeze test force, wearing the DEFO did not significantly affect force output according to any of the measures used to assess significance.

The follow up session shows that pain decreased on the pain at rest and ASLR right measures. The remaining scores remained stable.
Figure 4.4 Figures for case study two

A

B

C

D

E

F

G

H

I

J

K

L

M

N

Figure 4.4 Figures for case study two
4.4.3 Single Case Study Three (Figures 4.5 A-N)

This participant was a 62 year old female, presenting with unilateral adductor pain and SIJ pain which was aggravated by adduction based activities. Her sport was power walking, and she exercised three to five times a week.

Figure 4.5 A showed a significant increase in force output on the squeeze test, according to the celeration line and mean +2SD when the DEFO was worn. Some degree of carryover may be seen in figure 4.5 B which presents force output whilst wearing the control shorts. The PND statistic indicated that the DEFO was questionably effective (62.5%).

The pain scores vary across most of the outcome measures showing little effect of the DEFO upon pain. However a significant effect (below the celeration line) was observed for pain on the left leg ASLR (figure 4.5 I), with some possible carryover seen in the control condition (figure 4.5 J). The right leg ASLR pain was variable according to the celeration line. Pain scores remain under the celeration line suggesting a possible effect of wearing the DEFO, before rising above the celeration line for the last two measurement points. This suggests that pain had become irritated; maybe due to their condition or an increase in training load.

In the intervention phase pre broad jump pain was significantly reduced according to the celeration line, when the control shorts were worn. This was not seen when the DEFO was worn. The follow up session shows that any effect upon pain scores stabilised, but that squeeze test force had dropped.
Figure 4.5 Figures for case study three
4.4.4 Single Case Study Four (Figures 4.6 A-N)

This participant was a 29 year old female and she presented with SIJ pain. Her pain was aggravated by monthly hormone levels, and lengthy exercise periods, for example walking for three to four hours. Her sports were yoga, and aerobic/ power training programmes, and she exercised three to five times a week.

Figure 4.6 A shows a significant improvement (mean +2SD, celeration line and PND statistic of 100%) in squeeze test force production, when wearing the DEFO during the intervention phase. Some evidence of a carryover effect is suggested in figure 4.6 B.

Apart from pain on the squeeze test (which showed no change), the other pain-related outcome measures tended to remain under the celeration lines during the intervention phase, but showed no significant effects according to the mean-2SD or PND statistics.

The follow up session showed no further change.
Figure 4.6 Figures for case study four
4.4.5 Single Case Study Five (Figures 4.7 A-N)

This participant was a 53 year old female presenting with SIJ pain, but did not have clearly identifiable aggravating factors. She engaged in boxing training, and exercised five to seven times a week.

This participant showed that wearing the DEFO had a negative effect upon their squeeze test force output (figures 4.7 A and B) i.e. their force decreased significantly according to both the celeration line and the mean +2SD method.

Figure 4.7 E shows values for pain at rest under the predicted celeration line when the DEFO was worn, but pain then stabilises at zero. This may be the result of wearing the DEFO but may equally reflect the participant’s condition where, apart from slight increases in pain during the baseline, most pain scores indicated zero pain. Control shorts also indicated zero pain. The remaining outcome measures show that this participant had very little, if any, pain during testing (including the follow up session).

No other significant findings were observed for this participant.
4.4.6 Single Case Study Six (Figures 4.8 A-N)

This participant was a 26 year old female. She presented with SIJ pain which was aggravated by increased activity. Her sports were aerobic/ power training programmes and she exercised six days a week.

Figures 4.8 A and B shows that many of the force output values were above the celeration lines, indicating some improvement in the squeeze test. This was variable but showed a trend towards values staying above the celeration line in the latter stages of the intervention phase. However the mean +2SD method and PND statistic showed no significant findings. Similar observations were seen when the control shorts were worn during the intervention phase.

Pain scores on the squeeze test dropped to zero when wearing the DEFO, but this was not significant according to any of the measures of significance. This is discussed in section 4.5. Other outcome measures show that this participant experienced no pain during testing.

The follow up session indicates that force output increased after one month; both when wearing the DEFO or the control shorts. Pain scores show stability i.e. no pain.
Figure 4.8 Figures for case study six
4.4.7 **Single Case Study Seven** (Figures 4.9 A-N)

This person was a 42 year old female. She presented with SIJ pain which was aggravated by skiing. Her sport was skiing, and she exercised three to five times a week.

A significant improvement (according to values below the celeration line and mean+2SD) was seen for the squeeze test force during the intervention phase. This improvement is seen for both the DEFO and the control shorts (figures 4.9 A and B). The latter is also true for pain scores on the squeeze test; figures 4.9 C and D showing significant decreases in pain as assessed by the celeration line and mean -2SD method. The PND statistic confirms treatment effectiveness for reducing pain on the squeeze test (89%) but not for improved squeeze test force.

The remaining outcome measures show significantly decreased pain scores according to the celeration lines, and this is mirrored throughout the intervention phase (wearing either the DEFO or control shorts). No other significant findings were recorded.

At the one month follow up session, values show very little change for force output and pain scores.
Figure 4.9 Figures for case study seven
4.4.8 Single Case Study Eight (Figures 4.10 A-N)

This participant was a 34 year old female who presented with SIJ pain, aggravated by increased activity. Her sports were cycling and swimming and she exercised five to seven times a week.

Figure 4.10 C demonstrates a significant reduction in squeeze test pain scores (below the celeration line and mean +2SD, with a PND statistic of 100%) when the DEFO was worn. When wearing the control shorts pain fluctuations were evident.

Figures 4.10 E-N shows that during the intervention phase the pain scores for the remaining outcomes were all below the celeration line, when wearing either the DEFO or the control shorts No other significant findings were observed.

The follow up session shows that force output appears to improve when the participant is wearing either the DEFO or the control shorts, and the pre and post broad jump pain scores also drop.
Figure 4.10 Figures for case study eight
<table>
<thead>
<tr>
<th>Case Study/Measure</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Squeeze Test</strong></td>
<td>CI↑</td>
<td>↑ CI</td>
<td>↑ CI</td>
<td>↑ CI</td>
<td>↓ CI</td>
<td>↓ Cl</td>
<td>↑ Cl</td>
<td>Cl↑</td>
</tr>
<tr>
<td><strong>Force</strong></td>
<td>Msd↑</td>
<td>PND = 58.3%</td>
<td>Msd↑</td>
<td>PND =62.5%</td>
<td>Msd↑</td>
<td>PND =100%</td>
<td>Cl =</td>
<td>Msd↑</td>
</tr>
<tr>
<td></td>
<td>PND =12.5%</td>
<td>Cl = variable</td>
<td>PND = 0%</td>
<td>*</td>
<td>PND =0%</td>
<td>PND =25%</td>
<td>PND =33.3%</td>
<td>PND =88.9%</td>
</tr>
<tr>
<td><strong>Pain on Squeeze Test</strong></td>
<td>CI↓</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI (initially)</td>
<td>↓ CI</td>
<td>↓ Cl</td>
<td>↓ Cl</td>
<td>↓ Cl</td>
</tr>
<tr>
<td></td>
<td>PND = 8.3%</td>
<td>PND =25%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =88.9%</td>
<td>Msd↓</td>
<td>PND =100%</td>
</tr>
<tr>
<td><strong>ASLR Right</strong></td>
<td>CI↓</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
</tr>
<tr>
<td></td>
<td>PND=0%</td>
<td>PND=0%</td>
<td>PND =0%</td>
<td>PND =14.3%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
</tr>
<tr>
<td><strong>ASLR Left</strong></td>
<td>CI ↓</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
<td>↓ CI</td>
</tr>
<tr>
<td></td>
<td>PND=0%</td>
<td>PND=0%</td>
<td>PND=0%</td>
<td>PND =14.3%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
</tr>
<tr>
<td>Pain at Rest</td>
<td>CI ↓</td>
<td>↓CI</td>
<td>PND =0%</td>
<td>↓CI</td>
<td>↓CI</td>
<td>PND =0%</td>
<td>↓CI</td>
<td>↓CI</td>
</tr>
<tr>
<td>--------------</td>
<td>------</td>
<td>-----</td>
<td>---------</td>
<td>-----</td>
<td>-----</td>
<td>---------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td></td>
<td>PND= 0%</td>
<td>PND =25%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Pre Jump Pain</th>
<th>CI ↓</th>
<th>↓CI</th>
<th>PND =0%</th>
<th>↓CI</th>
<th>↓CI</th>
<th>PND =0%</th>
<th>↓CI</th>
<th>↓CI</th>
<th>PND =0%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PND = 25%</td>
<td>PND = 37.5%</td>
<td>PND =0%</td>
<td>PND = 14.29%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post Jump Pain</th>
<th>CI ↓</th>
<th>↓CI</th>
<th>PND =37.5%</th>
<th>↓CI</th>
<th>↓CI</th>
<th>PND =0%</th>
<th>↓CI</th>
<th>↓CI</th>
<th>PND =0%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PND = 8.3%</td>
<td>PND =75%</td>
<td>PND =14.29%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td>PND =0%</td>
<td></td>
</tr>
</tbody>
</table>

**Table 4.2 Summarising the change in clinical outcome measures**

CI indicates the change relative to the celeration line, whilst Msd indicates the change relative to the mean +/- 2 standard deviation line. ↓ indicates that during the intervention phase measures were below the celeration line. ↑ indicates that during the intervention phase measures were above the celeration line. Increases above the celeration line (↑) for the resisted adduction test indicates improvement in force production, whilst for the measures of pain a decrease (↓) indicates a decrease in pain. *Indicates that the pain dropped to zero. The PND statistic is shown as a percentage.
4.4.9 Group Analysis

The results of the group analysis, combining all of the participants using a randomisation test are shown in table 4.3. This highlights that as a group there was no significant effect of the DEFO or control conditions on any of the outcome measures tested.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Intervention (DEFO)</th>
<th>Control (Shorts)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at Rest</td>
<td>0.15</td>
<td>0.40</td>
</tr>
<tr>
<td>Force on Squeeze Test</td>
<td>0.26</td>
<td>0.38</td>
</tr>
<tr>
<td>Pain on Squeeze Test</td>
<td>0.17</td>
<td>0.54</td>
</tr>
<tr>
<td>Pain on Right ASLR</td>
<td>0.25</td>
<td>0.23</td>
</tr>
<tr>
<td>Pain on Left ASLR</td>
<td>0.19</td>
<td>0.16</td>
</tr>
<tr>
<td>Pre Broad Jump Pain</td>
<td>0.15</td>
<td>0.054</td>
</tr>
<tr>
<td>Post Broad Jump Pain</td>
<td>0.17</td>
<td>0.51</td>
</tr>
</tbody>
</table>

Table 4.3 Randomisation test p values for each outcome measure

These values indicate if there is a statistically significant difference between the actual changes in baseline to intervention scores compared with the randomly generated change when all participant scores are grouped together. The values compare the baseline scores to the scores obtained during the intervention period whilst wearing the
DEFO in assessment one (column two) and when wearing the control shorts in assessment two (column three)

4.4.10 Participant Subjective Reports

All participants reported that they would continue wearing the DEFO. Table 4.4 summarises the participant subjective reports.
<table>
<thead>
<tr>
<th></th>
<th>001</th>
<th>002</th>
<th>003</th>
<th>004</th>
<th>005</th>
<th>006</th>
<th>007</th>
<th>008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Did you wear the shorts for sport?</strong></td>
<td>Yes; certain sports which induced pain (football, squash)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Comfort for sport?</strong></td>
<td>Found them tight. Would only wear for sport</td>
<td>Reasonable</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Reasonable. Can feel hot</td>
<td>Yes</td>
<td>Reasonable</td>
</tr>
<tr>
<td><strong>Did you wear the shorts outside of sport?</strong></td>
<td>No</td>
<td>Yes; for work</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Comfort outside of sport?</strong></td>
<td>N/A</td>
<td>Yes; wears them all day at times</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes but are tight</td>
</tr>
<tr>
<td><strong>Cosmesis</strong></td>
<td>Yes</td>
<td>Yes; had them in black with stitching in team</td>
<td>Yes; liked them all in</td>
<td>Yes; would like a below</td>
<td>Yes</td>
<td>Yes; but would like more colours</td>
<td>Reasonable</td>
<td>Yes</td>
</tr>
<tr>
<td>Effect on performance?</td>
<td>Improved ability to continue performing once pain started.</td>
<td>Questioned if continued use may cause muscle atrophy / impact upon breathing</td>
<td>Decreases pain felt post rugby; helps when SIJ is irritable.</td>
<td>Improved posture</td>
<td>Felt better control over balance exercises; improved core stability</td>
<td>Felt more confident wearing them, but pain has been low.</td>
<td>Felt they aided balance and improved ability to complete power training (plyometrics)</td>
<td>Improved posture when taking skiing lessons; improved technique as a result.</td>
</tr>
</tbody>
</table>

Table 4.4 A summary of the questionnaire responses
4.5 Discussion

The figures relating to the case studies, with the exception of case study five, demonstrated a significant effect (improvement) from wearing the customised DEFO upon either pain and/or function according to at least one measure of significant change (table 4.2).

4.5.1 Trends

Detailed examination of the results for each of the outcome measures has identified some interesting trends in patient responses which may help clinicians build a profile of those who may benefit the most from wearing this DEFO.

4.5.1.1 Squeeze Test Force (Primary Outcome Measure)

Cases studies one, three, four and seven all demonstrated a significant improvement (above mean + 2SD on two consecutive occasions) in force output on the squeeze test whilst wearing the DEFO. This was also seen for the intervention phase when wearing the control shorts (except case four). The site of pain was considered as a possible explanation as to why this might be the case, but rejected as none of these cases have the same site of pain (table 4.1). Carryover effects from wearing DEFOs have been observed in other studies (Matthews et al., 2009), but these effects may vary across individuals and conditions. Further work is needed to explore carryover effects in athletic injury populations.

As a further possibility, the relationship between baseline force level and the change in pain was examined to seek a potential reason as to why these particular cases produced significant results. When the forces produced in the squeeze test were normalised by body weight, cases studies one, three, four and seven (i.e. those showing an improvement in the ASLR) had a lower baseline force output to kilogram of body weight compared to the other cases (0.8; 1.3; 1.6; and 1.5 N per Kg respectively). One
exception was case study six who also showed a low force output to body weight value (1.2 N per kg). Case study six did however show a trend towards improved force output according to the celeration line; an extended intervention phase may have made any improvement in force production clearer.

All of the cases (one, three, four and seven) that showed an improvement in force production with the intervention thus demonstrated a force output of less than two Newton’s per kg of body weight at baseline; values above two Newton’s were seen in the cases where the DEFO had no significant effect upon force output. It is also evident that each of these case studies presented with a fluctuating baseline on the squeeze test; possibly indicating that daily variations in pain were affecting function.

4.5.1.2 Pain on ASLR

All case studies except number six demonstrated bilateral pain responses during the ASLR test procedure. When the pain score differences between the right and left ASLR were calculated (to examine the size of the effect), cases one, three and seven demonstrated the biggest differences highlighting a more one sided, asymmetric presentation in pain. Furthermore when the resting pain score was subtracted from the ASLR score causing the most pain (to examine any functional impact upon pain), these same cases studies were observed as having the biggest differences. That is, those cases that showed an improvement in force production during the squeeze test, tended to have pain that was considerably aggravated by an ASLR mainly on the side of their presenting symptoms.

The ASLR is used as a functional indicator of the pelvis’ ability to effectively transfer loads from the upper to the lower limbs (Vleeming et al., 2008). Mens et al (2006a) suggests that those who have a positive ASLR will improve with the introduction of a belt, or something which provides stabilisation. This suggests that these individuals
(cases one, three and seven) may have a load transfer deficit; laxity may or may not be associated with this. Furthermore, Mens et al (2006a) has described how athletes who demonstrated increased force with a pelvic belt in situ, had higher self-reported pain levels in the week preceding the study; 68mm on a 0-100 mm visual analogue scale (range = 56-79mm; where higher numbers indicate greater pain). This was not the situation in the current study; the case studies which demonstrated significantly improved force output (mean + 2SD) whilst wearing the DEFO had moderate pain scores, and were not necessarily those experiencing the most pain (cases one, seven and eight). However, Mens et al (2006a) reported that this group also complained of lumbosacral pain and had a significantly longer duration of pelvic / groin pain; a finding which differs from the current study.

4.5.1.3 Resting and Functional Pain Levels

A comparison of baseline and intervention resting pain levels showed cases one and two had the most benefit from wearing the DEFO.

Case number two not only experienced the biggest reduction in pain for pain at rest, but also for ASLR right, and pre jump pain scores. They also showed significant decreases in ASLR left and post jump pain scores. This was clearly a case study which had a clinically significant improvement in pain but not force. This may be explained by the fact that this participant demonstrated SIJ hypomobility. SIJ hypomobility was diagnosed through a more thorough clinical assessment process (including tests of lumbosacral mobility). This was a one off extended assessment as this was an historical patient. This finding suggests that the DEFO may have another mechanism other than addressing any deficit in force closure. Drawing on discussions from earlier chapters (1 and 3), case study two may provide support for the notion that the DEFO is influencing proprioception. That is they demonstrated an improvement despite not showing deficits
in stability, leading one to hypothesise that a non-mechanical mechanism may underlie the improvement with the DEFO. One such mechanism could be an enhancement in proprioception.

4.5.2 Carryover Effects

As is shown in section 4.4 several participants (one, two, three and seven) demonstrated carryover effects after wearing the DEFO; that is there was still an improvement when they were wearing the ordinary (control) shorts. As was previously mentioned, cases one, three and seven showed significant effects (mean +2SD) in force production, whilst wearing ordinary shorts.

In terms of PND statistics case studies one, two, three and seven had figures which ranged from a “questionably effective” to “effective” treatment (Scruggs and Mastropieri, 1994) on selected outcome measures. Respectively these PND statistics were 66.7% for squeeze test force, 50% for pre broad jump pain scores, 75% for squeeze test force, and 100% for pain on squeeze test. Findings of a carryover effect after wearing DEFOs is in consensus with previous findings, albeit in a different patient population (Matthews et al., 2009).

Considering the various pelvic / groin presentations (sites of pain; duration, history etc.), it may be expected that some participants would show a stronger effect in terms of function (Mens et al., 2006a); whilst in others an effect upon pain is more apparent. More insight into the mechanism(s), and/or pathology associated with pelvic / groin pain may explain this, but this is an issue already acknowledged as being challenging (Ficek et al., 2008).

4.5.3 Participant’s Subjective Responses

All of the athletes reported (via a questionnaire; see appendix 2) that they would continue to wear the DEFO.
DEFO usage varied considerably; from participant one only wearing his DEFO for activities which caused him pain (football and squash) to participant two who wore the DEFO when playing rugby, and for eight to nine hours a day during periods of acute pain. Participant seven chose to wear their DEFO to aid their learning of a new skill, skiing, because they felt that it aided their stability. Participants two, three, four, six, seven and eight reported that wearing the DEFO improved their balance and/or posture (both with sport and/or everyday activities); case study six also reported that the DEFO improved their power training.

Apart from participant one, whose intention was only to wear the DEFO as part of his rehabilitation, the remaining participants reported that they would continue to wear the DEFO for other purposes such as pain control/ injury prevention, improved posture, and increased feeling of stability and core control.

4.5.4 Potential Explanations

An athletic DEFO and its effect upon athletic pelvic / groin pain is a novel concept; no comparable research exists to underpin a critique. However, findings from the pelvic belt literature may offer some explanations. Pelvic belts have been shown to significantly reduce pain and improve force output (as measured by the squeeze test) on athletes with adductor pain (Mens et al., 2006a), and significantly reduce pain in those with posterior pelvic pain (Östgaard et al., 1994).

Groin pain may arise from pelvic instability (Kinchington, 2012). The DEFO may address any deficit in form or force closure (Lee and Vleeming, 1998) by providing cylindrical pressure to improve loading and thus enhance stability.

Pelvic instability due to form or force closure deficits may be associated with some pelvic / groin presentations, but other mechanisms need to be considered. Mens et al (2001) explained how proprioceptive deficit and impaired muscle function may also be
a cause of pelvic / groin pain. Case study two, wherein the diagnosis included hypomobility at the SIJ, supports the notion that other mechanisms may also be involved.

In this case consideration should be given as to whether this DEFO addresses other causes of pelvic / groin dysfunction. Kraemer et al (1998) for example, demonstrated the ability of compression shorts to improve proprioception at the hip in both athletes and non-athletes, suggesting that enhancement of cutaneous receptors may have resulted in improved joint position sense. A similar finding was observed by McNair and Heine (1999) who found that lumbar bracing has the ability to improve trunk proprioception; more so in those with a proprioceptive deficit. Even elastic bandage compression has been shown to enhance knee proprioception (Perlau et al., 1995). Therefore improving joint position sense and proprioception may lead to an improvement in pain response, if as Mens et al. (2001) suggested alterations in this and muscle function may be linked with lumbopelvic pain and much as joint laxity. This may be important in cases where pain is associated with movement dysfunction, for example SIJ hypomobility.

Posterior tilting of the pelvis has been used clinically as an intervention to reduce pelvic / groin pain (Day et al., 1984). It is therefore possible that the DEFO may affect pain by posteriorly tilting the pelvis. However, further work is required to substantiate the relationship between pelvic posture and pelvic / groin pain (Day et al., 1984; Walker et al., 1987) and whether this could be influenced by a DEFO.

4.5.5 Group Comparisons; Randomisation Tests

The randomisation tests did not show any significant effect of intervention on any of the outcome measures (at the level ≤ 0.05). This may be the result of a type II error caused by insufficient power, but may also reflect the variability in the participant presentations.
Pre jump pain score (for the control condition) did demonstrate a trend towards decreased pain scores ($p = 0.054$); this may possibly reflect some degree of carryover from wearing the DEFO, but is mentioned with caution as trends were not seen in other scores.

These results support the conclusions drawn from the visual analyses, which highlighted considerable variation between the eight individuals in their response to wearing the DEFO. Some responded by significantly increasing their squeeze test force, others responded with significant decreases in pain scores on various outcome measures, whilst others showed little effect (case study five). This mixed picture may be explained by a number of factors. Firstly by the differing pelvic / groin conditions that presented and therefore the existence of varying aetiologies. Secondly in that some patients had more than one site of pain, and thus may be expected to respond differently. Finally, the low pain scores invoked by many of these tests may also have influenced the non-significant findings; the use of more stressful tests (discussed in chapter 3) may be useful. Future work should also explore the responsiveness of these tests within athletic population.

These explanations may be used to help inform the development of patient profiles, to categorise patient subgroups who may respond to this DEFO with reduction in pain and/or functional improvements.

4.5.6 Limitations

4.5.6.1 Outcome Measures

The selected outcome measures were based on standardised tests used clinically, and/or in pelvic belt research in athletic and non-athletic populations. However, on some of the measures (for example pain on ASLR) the lowest possible score for pain was elicited at baseline, which limits the potential for improvement to be demonstrated on these
measures. This may have influenced the findings, as discussed in more detail in section 4.5.6.2. Therefore, as discussed by Verrall et al. (2005) more stressful tests, may be more relevant for this population and need to be explored in future work. Furthermore as the ASLR was used out of context in order to explore its effect upon functional pain, further work in this area may benefit from using the test as it was originally designed, that is to rate the difficulty of performing the test (Mens et al., 1999); this was further discussed in chapter 2. This may also aid in refining the patient profile of “best responders.”

It may also have been useful to develop the questionnaire feedback using other qualitative methods. The use of a focus group at the end of the study may have facilitated more in depth discussion of the DEFOs perceived attributes.

4.5.6.2 Analyses Methods

With reference to the figures summarised in table 4.2, the calculated mean +/-2SD often represented a value less than zero. In terms of participants’ rating of their pain on the scale of zero to 10, less than zero is an invalid value. Therefore using this form of analysis did not always show a significant result even if a participant’s pain was consistently lower during the intervention phase. Russo (2003) describes how these “floor effects” demonstrate that this is likely to be a poor measure of performance. This again supports the notion of selecting more stressful measures of performance, in order to avoid these floor effects.

A further limitation is that several forms of analysis were used, which in certain circumstances were not always useful. For example, the PND line was of limited use with low pain levels; just one very low pain score in the baseline phase results in the PND line being set at this level, for example zero. This is a criticism which has been noted in the literature (Morgan and Morgan, 2009). Thus as there is no agreement on
how to analyse single case study research (Hojem and Ottenbacher, 1988), these findings further support the argument that a range of different methods may be needed to fully analyse data of this nature, with consideration given to the measurement scales of the selected outcome measures.

4.5.6.3 Sample

In terms of this sample of athletes, many of those tested had chronic pelvic / groin pain. Therefore conclusions can only be drawn for this specific group.

It may be that the studies were conducted over too short a timescale to ascertain the true effect of the DEFO on chronic conditions. Lower pain scores on follow up may indicate an improvement with time that could have been assessed with longer follow up.

This sample was comprised of non-elite athletes, which may be relevant in terms of the amount of training / recovery that they would undertake compared to elite performers. However even recruiting participants at this level was challenging; several potential participants were lost because 15 daily testing sessions conflicted with their own commitments (holidays, work and travel). Whilst a limitation has been discussed in terms of a non-elite sample being used, expert opinions declare the significance of even a small improvement in performance is considerable at elite level; 0.01 second being the difference between winning and losing in a 100 metre Olympic final (Behm et al., 2004). Whilst the opportunity to replicate this design with such athletes is seldom going to occur, elite athletes provide an opportunity to think about what constitutes a significant improvement in clinical signs (or performance) rather than just a statistically significant improvement.

Whilst efforts were made to optimise internal validity (Kazdin, 1981), it is acknowledged that this could be improved. Blinding of the investigator was not
employed during the testing period, and this is a potential source of bias which future work would need to eradicate.

4.5.7 Future Work

Bracing the core musculature (defined as local stabilisers of the trunk) has been shown to improve trunk proprioception (McNair and Heine, 1999). Compression shorts have also demonstrated to improve hip joint proprioception (Kraemer et al., 1998). Considering that research has demonstrated that a proprioceptive deficit of the trunk has been associated with increased risk of injuries affecting the knee and low back (Borghuis et al., 2008), and an association between female knee injuries and poor trunk proprioception (Zazulak et al., 2007); there may be a role for this DEFO in injury prevention. This is only conjecture at this stage; therefore the impact of the DEFO on proprioception is an area which is proposed for future work.

A further area of proposed work is the impact of the DEFO on performance. Considering some of the subjective responses from participants which related to performance benefits, the examination of the impact of the DEFO on a functional measure of balance and a field test of power may be a good starting point in which to consider the effect of this DEFO upon performance. As discussed in section 4.5.6.1 other qualitative methods may have provided a better understanding of the DEFO’s effect upon performance. Future work should consider using methods such as semi structured interviews or focus groups. The latter in particular has advantages in that it doesn’t discriminate against those with reading or writing difficulties, and can elicit responses from those who are reluctant to speak in a one-to one situation (Kitzinger, 1995). This may help understand why participants hold particular beliefs about the DEFO.
4.6 Conclusion

The nature of this series of single case studies and the time scale involved enabled detailed data to be collected; both objective and subjective. These results have indicated that the wearing of this customised athletic DEFO may have a positive effect upon the pain and/or function of some athletes with pelvic/groin pain. Furthermore, this case series provide preliminary information which is helpful in identifying a profile of patients who appear to respond positively to wearing this DEFO. There is some evidence indicating that a low force output (<2N per kg body weight) could be a useful predictor in terms of responding to the DEFO functionally.

In conclusion this DEFO may have a role in supporting the physiotherapeutic management of athletic pelvic/groin pain. Further work examining its impact upon proprioception may help in broadening our understanding of some of the mechanisms behind its function, and to ascertain if it may play both a preventative and rehabilitative role in the management of pelvic/groin pain. This may also help further our understanding of those patients who experience the most benefit from wearing this customised DEFO.

Further work is required in order to build upon the limitations of this case series design, develop the clinical evaluation of this DEFO, refine the current patient profile of responders, and investigate effects upon performance measures. In terms of performance measures it is important to understand the most appropriate methods of assessment. Chapter 5 explores the measurement of athletic balance, which was perceived by some of the case series participants as being positively influenced by wearing the DEFO.
Chapter Five Assessing Athletic Balance: A Systematic Approach to Reviewing the Literature

5.1 Introduction

Balance is a complex interaction between proprioceptive, visual, vestibular afferents and central nervous systems which impact upon the responding musculoskeletal system (Hahn et al., 1999; Bressel et al., 2007; Taube et al., 2008). Within sports medicine, assessing an athlete’s balance is a significant part of the clinical process (Emery, 2003), with an emphasis placed upon proprioceptive / balance exercises as both a tool for injury prevention (Guskiewicz and Perrin, 1996; Malliou et al., 2004) and as a rehabilitation strategy (Emery, 2003; Fredericson and Moore, 2005). However, the physical demands of sport are extremely diverse, and balance and postural control appear to be influenced by other performance attributes. For example, strength training programmes lead to significant improvements in both static (Romberg Test) and dynamic (Star Excursion Balance Test) measures of balance (Mohammadi et al., 2012; Mattacola and Lloyd, 1997).

Selecting an appropriate measurement tool is important for the effective assessment of athletic balance (Emery, 2003). In sport both unilateral balance and dynamic neuromuscular control have been identified as athletic requirements (Plisky et al., 2006), and therefore measurement tools need to reflect the different demands that sport places upon these balance systems. In clinical practice “outcome accountability” has become a professional necessity for ensuring that health gains are measured appropriately (Horner and Larmer, 2006). Within research appropriate measurement tools are used to establish whether an intervention leads to change, as well as the importance of this change (Johnson, 2008). This supports evidence based practice (Horner and Larmer, 2006)
To enable both clinicians and researchers to justify their selection of test, an appropriate measure needs to be able to demonstrate adequate psychometric properties. These psychometric properties are: (1) validity, measuring what it is designed to measure; (2) reliability, being able to demonstrate repeatability and precision (Kimberlin and Winterstein, 2008), and (3) responsiveness, the ability to detect clinically meaningful changes, whilst identifying stability where there is no change (de Vet et al., 2003). A measure’s psychometric properties must be demonstrated for the patient population it is intended for. This enables confidence in the test’s ability to measure what it is intended to measure, replicate the results with precision, and measure important change(s) if and when they occur.

To ascertain if a test demonstrates adequate validity, reliability and responsiveness, it is important to recognise that there are different types of each of these attributes, and therefore different methods of assessing them (Keszei et al., 2010). Collated from the wealth of literature on psychometric properties, table 5.1 provides a simple overview of these psychometric properties (Thomas and Nelson, 2001; Horner and Larmer, 2006; Bland, 2008; Atkinson and Nevill, 1998; Hayen et al., 2007; Tang et al., 2014; Husted et al., 2000; Weir, 2005). As the methods identified for assessing reliability, validity and responsiveness can be interpreted in different ways, where appropriate the interpretation used was presented within the text of this literature review.
<table>
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<th>Types of Validity, Definitions and Measures</th>
<th>Types of Reliability, Definitions and Measures</th>
<th>Types of Responsiveness, Definitions and Measures</th>
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<td>Content validity</td>
<td>Inter-rater reliability</td>
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<td>The ability to cover the concepts that have been defined for that particular measure.</td>
<td>The measurement agreement when multiple raters take the same measurements.</td>
<td>Measuring change over a pre-defined time period.</td>
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<td>Assessment relies on expert critique rather than a statistical measure.</td>
<td>Measures include intraclass correlation coefficients (ICCs), Bland Altman plots, and Kappa statistics.</td>
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<td>Criterion validity</td>
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<td>Comparing the scores of a test to the scores of a gold standard test of the same construct, is often used to establish if there is a relationship between the two tests.</td>
<td>The measurement agreement where a single rater is used to take the measurements on more than one occasion.</td>
<td>The change in measure over a pre specified period of time compared to the change in a “reference” measure.</td>
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<td>Measured by the identification of an</td>
<td>Measures include ICCs, Bland Altman plots, and Kappa statistics.</td>
<td>Measures include regression, correlation and receiver operating characteristics curves</td>
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and the correlation between the two (including Spearman’s Rank and Pearson’s product).

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<th>Construct validity</th>
<th>Internal consistency</th>
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<td>The relationship of a measure with theoretical concepts.</td>
<td>The degree to which items in a test or scale (that measure the same concept) are consistent in their scores.</td>
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<td>Measured include investigating the correlation between different measures.</td>
<td>Measures include the use of Cronbach’s Alpha, Kuder-Richardson 20, and the split half method.</td>
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Table 5.1 Summarising the types and measurement of validity, reliability and responsiveness

Informed by the previous discussion, the objective of the following literature review was to identify and appraise measures of athletic balance in a systematic manner.

5.2 Method

The specific topic to be searched was informed by using the PICO Framework to build a research question (da Costa Santos et al., 2007). Table 5.2 shows the process.
Table 5.2 Using PICO to build the research question

The emerging question was “what is the most valid, reliable and responsive measure for assessing athletic balance?”

5.2.1 Search Strategy and Eligibility Criteria

This literature review employed a systematic approach to searching using EBSCO to search the AMED/ CINAHL/ MEDLINE databases between 1990-Oct 2014 for English language, peer reviewed papers. Limits were used to retrieve up-to-date studies which were deemed to have met the standard for peer reviewed publication. Search terms appearing in the abstract were identified in order to answer the proposed question (table 5.2), and were structured and truncated as follows.
AB (athlet* or sport) AND AB (balance or postural stability or postural control) AND AB (test* or measure* or assess* ) AND AB (valid* or reliabil* or responsive* or clinimetric or psychometric)).

Inclusion criteria were studies employing one or more measures of balance / postural stability, which explored the reliability, validity and/or responsiveness of the measure(s) with adult athletes of any ability, and / or healthy participants. Reasons for excluding papers were; duplications, papers only investigating children, unpublished work, and those focusing on specific injuries for example concussion.

5.3 Results

The search yielded a total of 30 papers. After reviewing the abstracts, 10 were selected for full text reading.

Hand searching reference lists sourced a further five articles which were considered relevant to read as full text. The process by which relevant papers were identified is presented in figure 5.1 as a PRISMA flow diagram (Moher et al., 2009). Thirteen papers were selected for appraisal.
5.3.1 Data Extraction and Quality Assessment

Due to the nature of the selected papers, study quality was assessed using the QAREL checklist for reliability studies. The data extraction tool and explanatory method is summarised in Lucas et al. (2010). The QAREL checklist is presented in appendix 3, and is a tool which has been developed from an appraisal tool for diagnostic accuracy.
Best practice is to use QAREL in order to reach a peer consensus on quality, and answering yes to a question denotes acceptable quality in a study for that item (Lucas et al., 2010). The papers appraised scored yes for between one and six of the eleven items. There is no recommended score for deeming a paper of a particular standard; quality is assessed for each question item only, as numerical scoring systems can differ in the manner in which they weight different items (Lucas et al., 2010). One study, which scored only one yes answer and was unclear in many other areas of reporting, was excluded from the final review to give a total of 12 studies reviewed (Batson, 2010). Table 5.3 shows the completed quality assessment checklist for each study. Scores in each column reflect how well a study undertook a process or provided the information necessary to answer the question. The results show that there was a common lack of clarity in study reporting, resulting in them being scored as unclear in response to several question items. The quality assessment showed that the 12 papers selected ranged from low to moderately high in quality.
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<tr>
<td>Total</td>
<td>3</td>
<td>1</td>
<td>5</td>
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<td>1</td>
<td>5</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

**Low** | **Low** | **Moderate**

**Table 5.3 The quality assessment checklists**
5.3.2 Participants

A total of 592 participants were tested in the 12 studies (121 were female). Of these, there were 537 athletes and 55 healthy participants.

5.3.3 Tests

The measures of balance / postural control that were reported were grouped into force plate tests n = 6, the Star Excursion Balance Test (SEBT) n = 4, and other dynamic tests n = 2.

A brief overview of these tests is given below.

5.3.3.1 Force Plate Tests

Stabilometry involves using a force plate to measure excursions of the centre of pressure (Riemann et al., 1999a). It is used as the most accurate method of quantifying static unipedal balance, yet is limited by expense and lack of portability (Riemann et al., 1999b). Some studies have introduced protocols for evaluating dynamic balance, which include tilting force plates and sway, referencing them to ankle motion (Wikstrom et al., 2005; Naylor and Romani, 2006). Despite this, the ecological validity of static and dynamic modes is criticised for not reflecting the balance requirements seen in sport and whole body movements. A further criticism is that there is an over-emphasis on testing the relative contribution of proprioceptive information from the ankles (Perron et al., 2007).

5.3.3.2 The Balance Error Scoring System (BESS)

The BESS test is a clinical test which measures static balance in three stances; tandem, unipedal and bipedal, on two different surfaces (firm and foam). Participants are required to maintain a fixed position for 20 seconds without visual input; a standardised scoring system is used to record errors (Riemann et al., 1999b). A maximum of ten
errors can be scored for each condition; suggesting that the test may lack the responsiveness to measure small differences in scores, and lacks objectivity in that some components of the scoring scale require subjective judgements. The number of errors has been shown to increase with factors including ankle instability and concussion. However the BESS test may not pick up subtle changes in error scores (Bell et al., 2011).

5.3.3.3  **The Star Excursion Balance Test (SEBT)**

The SEBT is a tool which has been used to measure dynamic, postural control in athletes (Gribble and Hertel, 2003), and a functional test used to monitor progression during rehabilitation and to identify those at risk of lower limb injury (Filipa et al., 2010). It assesses multi-directional balance involving reaching from a unipedal stance, in four to eight different directions with the contralateral limb. The test is performed separately on both legs in order to compare the distances reached. The difficulty in comparing studies on the SEBT stems from a lack of consistency in the protocols adopted. However, although there is little consensus as to the numbers of trials, the need for practice trials and multiple test trials as part of a defined protocol is accepted practice (Kinzey and Armstrong, 1998; Hertel et al., 2000; Munroe and Herrington, 2010). Modified versions have also been investigated in attempts to make the test sport specific (Batson, 2010) and improve repeatability such as the Y-test (Plisky et al., 2009).

5.3.3.4  **The Multiple Single-Leg Hop-Stabilization Test (MSLHST)**

The MSLHST is a functional test that requires athletes to hop to 10 taped squares placed in a series of diagonal and transverse positions; holding each position for five seconds. Distances between squares are dictated by the individual’s height, and the test is scored
from a standardised checklist of balance and landing errors. Error scores consider performance of both the tested limb and the contralateral limb (Riemann et al., 1999a).
### 5.3.4 Synthesis

Table 5.4 presents a summary of the studies reviewed.

<table>
<thead>
<tr>
<th>Study</th>
<th>Balance / Stability Measure Examined</th>
<th>Sample Attributes</th>
<th>Psychometric Properties Tested</th>
<th>Summary of Results</th>
<th>Main Strengths/ Weaknesses</th>
</tr>
</thead>
</table>
| Ageberg et al (1998) | Stabilometry measures and the one leg hop test | 75 active participants  
Females =39  
Mean age =29.4 | Test retest reliability.  
Reliability of consecutive tests.  
Presence of learning / fatigue effects | ICCs:  
Stabilometry measures 0.68-0.83*  
Single leg hop test 0.96  
Mean CIs = 175.5-188.7cm (test one)  
178.1-191.7 (test two)  
Correlation between consecutive tests: | The study contributed preliminary data on the test retest reliability of the one leg hop test.  
The type of ICC used was not reported. |
<p>| Burnstein et al (2011) | Dynamic balance test involving timed unipedal stance on a foam pad, with eyes closed | 238 Cirque du Soleil athletic performers | Females =39 | Mean age 28.7 | Test retest reliability | ICC (2,1) range 0.23-0.51 over 18 months of tests. Between the 6-18 months test period ICC=0.46 | Although realistic in terms of how data is being gathered in this environment, the study isn’t reproducible as there are too many unknown variables such as different testing locations, different testers, and |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Test Name</th>
<th>Number of Participants</th>
<th>Duration</th>
<th>Reliability Measures</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hertel et al (2000)</td>
<td>Star Excursion Balance Test (SEBT) (8 directions)</td>
<td>16 active, 8 females</td>
<td>16 years</td>
<td>ICCs (2,1) range 0.37-0.55</td>
<td>Learning effects noted with best scores on trials 7-9. Intra-rater ICCs (2,1) range 0.78-0.96 SEM = 1.60-3.38 cm. Inter-rater ICCs range Day 1 0.35-0.84 SEM = 3.40-4.96 cm; Day 2 0.81-0.93 SEM = 2.27-3.87 cm. Contributed new inter-rater reliability data. The authors claim high reliability but day 1 inter-rater reliability doesn’t support this.</td>
</tr>
<tr>
<td>Kinzey and Armstrong (1998)</td>
<td>SEBT (4 directions)</td>
<td>20 healthy volunteers, 11 females</td>
<td>20 years</td>
<td>ICCs (2,1) range 0.67-0.87</td>
<td>Test retest reliability SEM = 3.43-4.78 cm (after 5 trials in each) Early SEBT work which used only 4 directions of movement. Didn’t normalise for leg length.</td>
</tr>
</tbody>
</table>
Meshkati et al (2011) | Force platform measures (centre of pressure) with eyes open and eyes shut, before and after fatigue | Age range =18-35 | Test retest reliability | ICC (2,3) for each condition*  
Athletes: No fatigue, eyes open 0.48-0.73  
No fatigue, eyes closed 0.69-0.89  
Fatigue, eyes open 0.51-0.80 | Wide CIs on the ICCs on many measures. Results may be gender and sport specific, and static bipedal stance measures are not seen to reflect athletic balance.  
Spearman Brown Prophecy indicated that 6 practice sessions of 5 trials in each direction was needed to improve reliability to a minimum of 0.86 in all directions.  
15 male karateists Mean age =21.47  
16 male non-athletes Mean age =21.5 years
<table>
<thead>
<tr>
<th></th>
<th>Fatigue, eyes closed 0.71-0.89</th>
<th>Non-athletes: No fatigue, eyes open 0.28-0.73</th>
<th>No fatigue, eyes closed 0.62-0.73</th>
<th>Fatigue, eyes open 0.34-0.79</th>
<th>Fatigue, eyes closed 0.63-0.90</th>
</tr>
</thead>
</table>


<p>| Munroe and Herrington (2010) | SEBT (8 directions) | 22 mixed sex, recreational athletes&lt;br&gt; Females = 11&lt;br&gt; Mean age = 22.3&lt;br&gt; Male mean age = 22.8 years | Test retest reliability&lt;br&gt; Error scores | ICC (3,1) range 0.84-0.92&lt;br&gt; SEM = 2.21-2.94 cm | Leg length used to normalise reach values.&lt;br&gt; Standardised protocol used which reflects common practice, but athletes had bare feet.&lt;br&gt; Also presented CIs alongside ICCs, which were narrow |
| Naylor and Romani (2006) | Neurocom Balance Master: 3 dynamic tests conducted on a force plate.&lt;br&gt; Forward lunge&lt;br&gt; Step up and over&lt;br&gt; Step quick turn | 15 active females&lt;br&gt; Mean age = 24.2 years | Intra and inter rater reliability | Inter-rater ICCs (3, k)&lt;br&gt; Forward lunge 0.71-0.91&lt;br&gt; CIs= 0.18-0.97&lt;br&gt; Step quick turn 0.72-0.88&lt;br&gt; CIs = 0.41-0.95&lt;br&gt; Step up and over 0.59-0.87&lt;br&gt; CIs = 0.14-0.94&lt;br&gt; Intra-rater | Gender specific.&lt;br&gt; Confidence intervals were very wide on several variables, urging caution in concluding reliability |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Test Description</th>
<th>Participants</th>
<th>Inter and intra-rater reliability</th>
<th>ICCs (3, k)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plisky et al (2009)</td>
<td>Modified SEBT:Y test (3 directions)</td>
<td>15 collegiate, male footballers, Mean age = 19.7</td>
<td>Inter-rater ICC (3,1): 0.85-0.91, SEM = 2.01-5.84 cm, Inter-rater ICC (2,1) ranged from 0.99-1.0, SEM = 0.68-3.31cm</td>
<td>Forward lunge 0.76-0.93, CIs = 0.50-0.97, Step quick turn 0.70-0.78, CIs = 0.38-0.89, Step up and over 0.68-0.92, CIs = 0.08-0.96</td>
<td>Narrow CIs for ICC’s for inter-rater reliability; and moderate for intra-rater reliability. Data was normalised for leg length. Results could be sport / gender specific</td>
</tr>
<tr>
<td>Riemann et al (1999a)</td>
<td>Multiple single-leg hop-stabilization test</td>
<td>30 active people</td>
<td>Inter rater reliability</td>
<td>ICC (2,1)</td>
<td>The MSLHST may be a useful functional test which reflects the nature of many sports.</td>
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<tr>
<td></td>
<td></td>
<td>Females = 11</td>
<td>Balance scores</td>
<td>0.70-0.74</td>
<td>Scoring could be influenced by subjectivity but effort was made to objectify scoring where possible.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mean age =</td>
<td>SEM = 0.54-0.55</td>
<td></td>
<td>Test re test reliability needs investigating</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.23 years</td>
<td>Landing scores</td>
<td>0.92</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>SEM = 0.56-0.57</td>
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<td><strong>SEM = 0.54-0.55</strong></td>
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<td></td>
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<td></td>
<td><strong>Landing scores 0.92</strong></td>
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<td><strong>SEM = 0.56-0.57</strong></td>
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<td><strong>SEM = 0.54-0.55</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td><strong>Inter rater reliability</strong></td>
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<td></td>
<td></td>
<td><strong>BESS inter-rater reliability</strong></td>
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<td></td>
<td></td>
<td></td>
<td>ICC’s (2,1) range 0.78-0.93</td>
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<tr>
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<td></td>
<td></td>
<td>SEM = 0.04-0.56</td>
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<td></td>
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<td></td>
<td>Significant (p = &lt;0.001) but variable correlations with stabilometry</td>
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<td></td>
<td></td>
<td></td>
<td>r = 0.31-0.79</td>
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</table>

<table>
<thead>
<tr>
<th>Riemann et al (1999b)</th>
<th>Stabilometry measures and the Balance Error Scoring System (BESS) test scores</th>
<th>111 male varsity athletes</th>
<th>Inter rater reliability</th>
<th>BESS inter-rater reliability</th>
<th>Didn’t look at total BESS score.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean age = 19.8 years</td>
<td></td>
<td></td>
<td>Couldn’t evaluate double leg stance on firm surface as there was zero variance i.e. no errors were made by participants.</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Study indicates a link between functional balance measures and stabilometry.</td>
</tr>
<tr>
<td>Schmitz and Arnold (1998)</td>
<td>Single leg stability using Biodex system. Looking at Overall stability index (OSI) and foot position measures on a tilting force plate</td>
<td>19 university students not currently engaged in varsity sport Females =11 Mean age = 24.4 years</td>
<td>Intra and inter rater reliability</td>
<td>The OSI scores had the highest ICCs (2,1); inter-rater (0.70) SEM = 0.90 and intra-rater reliability (0.82) SEM = 0.69 Foot position scores ranged from inter-rater 0.54-0.93 SEM =0.28-2.51 and intra-rater 0.55-0.81 SEM = 0.56-2.19</td>
<td>Participants were not actively involved in sport. Reporting errors were evident in the paper. The test protocol is time consuming due to the familiarisation session required.</td>
</tr>
</tbody>
</table>
Table 5.4 A summary of the 12 studies selected for review

<table>
<thead>
<tr>
<th>Study</th>
<th>Measure</th>
<th>Participants</th>
<th>Feasibility, test retest reliability and precision</th>
<th>DPSI retest reliability</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wikstrom et al (2005)</td>
<td>Biodex Stability System used to calculate Dynamic postural stability index (DPSI) to compare with time to stabilisation (TTS)</td>
<td>18 active participants</td>
<td></td>
<td></td>
<td>Examined a new measure, which was dynamic and showed very good test retest reliability. Compared to TTS, CI were narrow for the DPSI and wide for TTS. An expensive test best suited to lab conditions.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Females = 11</td>
<td></td>
<td>DPSI retest reliability</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Mean age =23 years</td>
<td>ICC (3,1) = 0.96 SEM = 0.3</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Male mean age = 22 years</td>
<td>TTS ICC(3,1) 0.66 SEM = 2.10</td>
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</tbody>
</table>

ICC = Intraclass Correlation Coefficient
SEM = Standard Error of Measurement
CI = 95% Confidence Intervals.

Mean age is expressed in years

*Studies using stabilometry measures use a wide range of variables using different measurement scales. Studies giving the CIs and SEMs only for mean values are not reported and should be viewed in the original paper.
Following the discussion of methods of measuring reliability (section 5.1), for the purposes of this review ICCs were interpreted as follows; ICC < 0.40 = poor reliability; ICC ≥ 0.40 but ≤ 0.75 = fair to good reliability; and ICC > 0.75 = excellent reliability (Fleiss, 1986). Clinically acceptable reliability was defined as ICC ≥ 0.70 (Fitzpatrick et al., 1998).

5.3.4.1 Force Plate Tests

Six studies used force plates as a measurement tool; of these five studies incorporated a dynamic measure, and all focused upon different types of reliability. They were assessed as low to moderate quality in their ability to meet the QAREL question items (table 5.3).

One moderate quality study looked at the intra-rater reliability of bipedal stance stabilometry in athletes at two sessions over a 72 hour period (Meshkati et al., 2011). Results reported fair to excellent reliability with mean ICCs ranging from 0.48-0.89, although the very wide confidence intervals are important to note (-0.04-0.96) as these indicate that reliability is far more variable. Other test retest reliability studies have shown unipedal stance stabilometry is less reliable (ICC = 0.68-0.83) than unipedal functional tests (ICC = 0.96); the type of ICC, however, was not described (Ageberg et al., 1998).

There was moderate quality evidence that more dynamic measures such as the Dynamic Postural Stability Index (DPSI) had excellent test retest reliability (ICC =0.96; 95% confidence intervals not given) and precision (SEM = 0.3) in comparison to the more common measure of time to stabilisation (TTS) (Wikstrom et al., 2005).

Both intra and inter-rater reliability vary according to the stabilometry measures selected (Schmitz and Arnold, 1998). Using the Biodex Stability System (a tilting
platform) a range of variables were recorded from a single-leg stance, including the anterior/posterior stability index, the medial/lateral stability index and the overall stability index (OSI). Although intra-rater reliability was higher (ICC = 0.82) than inter-rater (ICC = 0.70) reliability when the OSI was calculated, there was considerably more variability when other stabilometry components of the index were examined such as the medial-lateral stability index (ICC = 0.42-0.43). This study also found that participant foot position showed varying degrees of reliability according to the measure used. The heel position in the y (medio-lateral) axis showed less intra- and inter-tester reliability (ICC = 0.55 and 0.54) than the foot angle (0.81 and 0.77) and heel in the x (antero-posterior) axis (ICC = 0.75 and 0.93); 95% CI were not given.

A similar finding was shown with the BESS clinical test, where inter-rater reliability varied according to balance conditions, ranging from ICC = 0.78 for the bipedal stance on foam to 0.96 for tandem stance on a firm surface (Riemann et al., 1999b). However these findings came from low quality studies, 95% CI were not presented and therefore the results should be interpreted with caution.

Moderate quality evidence has demonstrated that data from functional tests (table 5.4) undertaken on force plates (Neurocom Balance Master) has good to excellent inter (ICC = 0.59-0.91) and intra reliability (ICC = 0.68-0.93) (Naylor and Romani, 2006). This differs from static measures looking at vertical ground reaction forces, by looking at horizontal forces and weight generated forces during movement (Naylor and Romani, 2006). However 95% CI were very wide on some variables, for example the left lift up index for the step up and over test had CI ranging from ICC = 0.08-0.89. This suggests that consideration of what exactly needs to be measured is important, as in the same functional test the impact index (concentric lifting force of the leading leg) had the best reliability (intra and inter-rater reliability ICC = 0.83 (0.63-0.92).
Other factors that have affected the reliability of stabilometry tests are the presence of learning effects (Ageberg et al., 1998). The use of a familiarisation session and multiple trials have been adopted to mitigate these effects, but the number of necessary trials depends on the type of test used. For example Ageberg et al. (1998) found that the third trial resulting in the best balance performance. This is in consensus with other performance measures such as the standing long jump, which records the third trial or attempt to allow for learning effects (Almuzaini and Fleck, 2008).

One study measured validity (Riemann et al., 1999b). In terms of criterion validity significant positive correlations (p = <0.05) between a clinically used measure (BESS) and stabilometry target sway measures were reported. However these correlations range from weak to strong (Rumsey, 2011) (r = 0.3077 to 0.7887), suggesting that validity relates to specific test conditions. For example, the strongest correlation was seen between sway and the BESS test single leg stance on a foam surface, while the weakest correlation was seen between sway and double leg stance on a foam surface. No other studies explored validity, and responsiveness was not investigated in any of these studies.

5.3.4.2 Star Excursion Balance Test (SEBT)

Four studies investigated the SEBT; albeit using different protocols and modified versions. All studies focused on reliability and ranged from low to moderately high in quality.

Test retest reliability of the SEBT ranged from ICC = 0.67 to 0.96 (Kinzey and Armstrong, 1998; Munroe and Herrington, 2010; Hertel et al., 2000). This consistently improves to a clinically acceptable level >0.70 (Fitzpatrick et al., 1998) when the full eight direction test is used (Hertel et al., 2000; Munroe and Herrington, 2010). Although 95% confidence intervals were not determined, SEMs are shown in table 5.2. Further, a
study of moderately high quality found even higher test retest reliability (ICC = >0.85) on a three direction instrumented version of the SEBT; the Y test (Plisky et al., 2009).

Whilst the studies of SEBT differed in the number of test trials undertaken, like stabilometry this type of test requires a familiarisation process and multiple test trials to account for the significant learning effect recorded in early trials (p =<0.05) (Munroe and Herrington, 2010; Hertel et al., 2000). These learning effects may also influence the reliability of the SEBT. Large differences have been observed with ICC’s ranging from 0.35 to 0.84 in session one and 0.81 to 0.93 in session two which may highlight a learning effect in those conducting the test and/or an improvement in participants’ skill level with practice (Hertel et al., 2000). However, stronger evidence for using the more standardised Y test is shown with excellent inter-rater reliability findings (ICC = 0.99-1.0) with very narrow CI’s (0.92-1.0) (Plisky et al., 2009).

One study gave an indication of a meaningful change in score on the SEBT in healthy athletes (Munroe and Herrington, 2010). Using the smallest detectable difference (SDD), to show at what level of score the change is a “real” change and not just measurement “noise”, a real effect upon performance is indicated by a 6.13-8.15 % change in scores.

5.3.4.3 Other Dynamic Tests

Two studies using functional and/or dynamic tests of balance were included in the review. Both studies were moderate quality reliability studies, but showed conflicting reports of reliability.

A study conducted by (Riemann et al., 1999a) into the multiple single-leg hop-stabilisation test (MSLHST) found good to excellent inter-rater reliability (ICC = 0.70-0.92; SEM=0.54-0.57). However scoring on the balance component of the test showed
significant improvement with repeated testing (p<0.05) suggesting that, like the SEBT and stabilometry measures (Ageberg et al., 1998; Hertel et al., 2000), learning effects need to be accounted for in the protocol. Validity was not explored in this study.

In contrast the test retest reliability of a dynamic test similar to one of the BESS test conditions showed poor to fair reliability (ICC = 0.06-0.51) (Burnstein et al., 2011); although this may have been influenced by the use of previously gathered data with uncontrolled variables such as testing location and multiple testers. Earlier work comparing stabilometry with the BESS test showed that this similar BESS condition had excellent inter-rater reliability (ICC = 0.92). Burnstein et al. (2011) did not explore other psychometric properties of the balance test.

5.4 Discussion

Effective evaluation of athletic balance requires an appropriate measure; therefore knowledge of the psychometric and clinimetric properties of a test is essential in order to determine its suitability.

The 12 studies reviewed, which were rated as low to moderately high quality according to the QAREL checklist criteria, focused primarily upon reliability. There was a paucity of information regarding other properties such as validity and responsiveness.

Whilst force plate measures are seen as the most objective means of measuring postural control (Hertel et al., 2000), some consider them too static for athletes, and unable to assess the control of a non-weight bearing limb in maintaining unipedal stance when moving (Riemann et al., 1999a). There were mixed reports of the inter and intra-rater reliability of stabilometry. Whilst the ICCs generally indicated fair to excellent reliability, the CI’s (where available) were often very wide, suggesting caution should
be undertaken in interpretation of the results. The DPSI showed moderate quality evidence of excellent test retest reliability and precision (Wikstrom et al., 2005).

However, the need for lengthy familiarisation sessions and trials, and the use of force platforms and computer systems means that this type of measure may be more appropriate for laboratory based research.

Correlations between the stabilometry measures (sway measures) and the BESS test indicate that relationships may exist between specific laboratory based and clinically based objective measures of balance (Riemann et al., 1999b), but better quality evidence is needed to substantiate this. These correlations varied according to the condition examined (r = 0.3077 to 0.7887), and as discussed in section 5.3.4 only certain test conditions showed a strong correlation.

The SEBT has shown moderate quality evidence of clinically acceptable inter and intra-rater reliability when practice and multiple testing trials are used; but there lacks consensus on the number of trials. There is also an indication of a real change in performance score on the SEBT in healthy athletes. Although identified as an appropriate test of dynamic balance in athletes (Hertel et al., 2000), its validity has not been tested. However, this is confounded by the lack of a gold standard test with which to compare the SEBT.

Moderate to high quality evidence suggests that the Y test may offer a reliable and feasible method of assessing balance, as it is more standardised in its measurement and less time consuming than the SEBT, and shows excellent reliability (Plisky et al., 2009). A limiting factor for this type of reaching test is that it may still be considered a fairly static test for athletes (Batson, 2010), and therefore may not realistically measure the dynamic demands that are required in sports. Furthermore, reaching tests do not assess
the quality of movement during single leg reaches which is important to aesthetic sports such as dance and gymnastics.

From a functional field test perspective, the MSLHST study showed moderate quality evidence of clinically acceptable inter-rater reliability across repeated static (balance) and dynamic (landing) conditions. However, an indication of the presence of learning effects on the balance score component suggests the need for further investigation. Further work is also warranted to explore the test retest reliability and responsiveness of the MSLHST. Although its validity is unknown, on face value this is a test which challenges both the unilateral balance and dynamic neuromuscular control identified as athletic requirements (Plisky et al., 2006).

Tests such as the SEBT, BESS and MSLHST are being increasingly used because they are more time efficient, require little equipment and are therefore feasible to implement within the realities of the pressured clinical environment (Riemann et al., 1999a; Munroe and Herrington, 2010). However, with limited quality evidence and a lack of comprehensive information to base decisions upon, the results of the data generated should be interpreted in this light and with the view to undertaking further investigation.

5.4.1 Limitations of the Review

Although QAREL is an appropriate tool for evaluating the quality of reliability studies, as discussed in section 5.3.1. best practice is for multiple reviewers to use the QAREL checklist as a peer assessment process so that a consensus can be reached on all question items and minimise bias (Lucas et al., 2010). In this thesis this process may have been limited by the use of one reviewer. Bias may have been introduced by selecting only English language papers, relying on electronic databases as the primary search tool, and in hand searching the reference lists (Cipriani and Geddes, 2003). Finally, the decision not to include injury specific balance test studies for this review.
5.5 Conclusions and Recommendations

An appropriate assessment of athletic balance is necessary for identifying those with injury risks (Plisky et al., 2009), monitoring the effectiveness of injury prevention training (Emery, 2003), and for measuring rehabilitation progress (Riemann et al., 1999b). Based upon the evidence reviewed there is not a clear answer to the question posed in this review “what is the most valid, reliable and responsive measure of assessing athletic balance?” Moderate level evidence suggests that the MSLHST appears to reflect the landing and balance demands of sport better than static stabilometry or BESS. The MSLHST scoring system also shows that the quality of an athlete’s balance is better assessed than in the SEBT or Y tests, which only measure single stance reach distance. This makes it appropriate in sports which include a quality of movement component, such as gymnastics. Further its inexpensive and portable nature makes it an appropriate test to be used in field or laboratory locations. However, its intra-rater reliability and responsiveness requires investigation. Other more time consuming and expensive measures such as the DPSI may be better suited to laboratory based research (Wikstrom et al., 2005).

In consensus with Emery (2003), and based on these findings, there does not appear to be a gold standard measure for athletic balance, and it is unlikely that one measure could encompass all athletes. Athletic balance is not easily definable and appears too complex to be measured out of context (Guskiewicz and Perrin, 1996). Justifying the selection of any test must consider for who, what, and in which context the results are
being interpreted. Caution should be taken in selecting a measure due to the need for more rigorous evidence, and information on validity and responsiveness.

Chapter 6 focuses upon one of the balance measures reviewed, the MSLHST, in order to assess its appropriateness for use in future work. For this purpose the intra-rater reliability of this measure was of interest.
6 Chapter Six Examining the Intra-Rater Reliability of the Multiple Single-Leg Hop-Stabilisation Test and Relationships with Leg Dominance, Age and Training

6.1 Introduction

Normal balance requires the interaction between multisensory organ systems (proprioceptive, visual and vestibular (Peterka, 2002)) and systems of the brain and spinal cord, which ultimately control the multi-jointed musculoskeletal system (Hahn et al., 1999; Bressel et al., 2007; Taube et al., 2008). These systems can be affected by factors such as nutrition (Swanenburg et al., 2007), age (Barnett et al., 2003), injury (Wikstrom et al., 2010) and disease (Allet et al., 2010). At an optimal level they work to maintain the centre of gravity within a defined base of support, and the task specific orientation of body parts (Massion, 1998).

Chapter 5 discussed the importance of assessing an athlete’s balance, but despite the implementation of balance training for both injury prevention and rehabilitation, no gold standard outcome measure exists with which to quantify balance within the athletic population (Emery, 2003). Whilst it is acknowledged that balance can be measured statically or dynamically, the population being examined should direct the nature of the test selected. Further, it should not be assumed that static balance ability is positively correlated with dynamic balance performance (Hrysomallis et al., 2006). Therefore it appears appropriate to use a dynamic measure of balance when examining the athletic population; this “dynamic” attribute being apparent in all sport.

The need to measure athletic balance stems from the results of the case studies presented in chapter 3 that evaluated the use of a customised dynamic elastomeric fabric orthosis (DEFO) in athletes. Questionnaire responses from the participating athletes suggested that the DEFO (in the form of shorts) may have had a positive effect upon
balance (Sawle et al., 2015). In order to investigate whether this is the case the intention is to incorporate a functional measure of athletic balance in future clinical trials. On the basis of the literature appraised in chapter 5, and discussion with clinical colleagues, it is anticipated that a functional single leg test may be an appropriate measure of dynamic balance. Previous research has found that knee instability is positively correlated with one-legged tests (Risberg and Ekeland, 1994), and that a single leg hopping test can be a reliable means of assessing ankle joint performance. The MSLHST is a single leg functional measure of stability (Riemann et al., 1999a), and was briefly explained in chapter 5. Athletes are scored on both a balance and landing scale, according to the errors that they commit in each period of the test; these scores are summed to give the total error score. This test is an adaption of the Bass test (Johnson and Nelson, 1986) which was subsequently modified by Riemann et al. (1999a) who argue that this type of functional test is important because it challenges athletes in a way which reflects the forces and directions of movement that are integral to sport.

Although Riemann et al. (1999a) reported that this test has very good inter-rater reliability (ICC = 0.70-0.92), intra-rater reliability was shown to be lacking in detail and data were incomplete. Closer inspection of the reported intra-rater reliability reveals that this only refers to the balance scores which significantly differed between tests; no significant difference were observed with the landing scores (Emery, 2003). Further, Riemann et al. (1999a) assessed three test sessions, each 48 hours apart; a different scenario to the current intra-rater reliability study in which the testing is completed in one session.

A further consideration for any balance study involving athletes with a lower limb injury is the influence of lower limb dominance. In football, a players’ dominant (preferred kicking leg) has shown to be significantly stronger than their non-dominant
leg in terms of hip adductor strength (Thorborg et al., 2011), and hip flexor strength (Hanna et al., 2010), but not in all muscle groups, for example hip abductors (Thorborg et al., 2011). It has been suggested by Thorborg et al. (2011) that any rehabilitation of injury needs to take leg dominance into consideration. As a strength deficit may potentially impair balance, it is important that a study considers the role of leg dominance, and ascertains if this influences the reliability of the balance measure used.

### 6.1.1 Aim of study

To assess the intra-rater reliability of a functional measure of athletic balance; the multiple single-leg hop-stabilisation test (MSLHST) on the dominant and non-dominant legs.

### 6.2 Design

A test retest design was employed. All of the testing was undertaken by a single investigator (LS), using portable equipment; the test was scored in “real time” while the balance measure was being performed.

#### 6.2.1 Participants

A convenience sample of volunteers was recruited from the staff and students at Plymouth University, and from local sports clubs. To maximise recruitment the study was conducted at the University (Human Movement Laboratory) to accommodate the staff and student participants. Ethical approval was gained from the Faculty of Health and Human Science Ethics Committee, Plymouth University; 12/2012.

#### 6.2.2 Eligibility Criteria

##### 6.2.2.1 Inclusion Criteria:

Over 18, and able to give informed consent

Self-declared as healthy, with no lower limb musculoskeletal injuries in the last three months.
6.2.2.2 **Exclusion Criteria:**

Current Pregnancy - to avoid putting the mother and foetus at risk.

Current illness / unresolved condition – which may put the participant at risk of further illness.

Neurological, musculoskeletal or cardiorespiratory impairment – which would be a confounding factor, and/or put the participant at higher risk of injury.

### 6.2.3 Sample Size

Reliability coefficients greater than 0.7 are deemed to be acceptable for most clinical trials (Fitzpatrick et al., 1998). A power calculation indicated that 15 people were needed to be recruited in order to demonstrate an ICC of >0.7 (power = 0.88; α = 0.05). This is in keeping with the work of Fleiss (1986) and their discussion of the numbers required for a reliability study involving quantitative measures.

### 6.3 Procedures

#### 6.3.1 Participant Characteristics

Participant demographics (age, gender, height, weight), their leg dominance (as defined by which side they would kick a ball), and the average number of hours spent training / performing sports in a week were recorded.

#### 6.3.1.1 Measurement of the MSLHST

Testing was undertaken in standard sports attire (shorts, t-shirt and trainers) and conducted in the same undisturbed environment, in order to minimise external influences and allow for standardisation. Standardised written instructions were given to all participants prior to testing; this included photographs of stances (recreated from those illustrated by Riemann et al. (1999a)). Participants also received verbal
instructions from the researcher whilst viewing the MSLHT and before completing their practice attempts.

The distances between each of the boxes (see figure 6.2) were standardised according to the participants’ height. Diagonal distances represented 45% of the participants’ height (wearing trainers), and Pythagoras Theorem used to calculate the distances for adjacent boxes. The mat was labelled according to the height related distances prior to testing to ensure that during testing, there was minimal delay in setting up the mat. This was achieved using hook and loop combinations of numbered Velcro® squares.

<table>
<thead>
<tr>
<th>Height in Centimetres (cm)</th>
<th>Diagonal Distance (cm)</th>
<th>Adjacent Distance (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>150-159.9</td>
<td>70</td>
<td>49</td>
</tr>
<tr>
<td>160-169.9</td>
<td>74</td>
<td>53</td>
</tr>
<tr>
<td>170-179.9</td>
<td>79</td>
<td>58</td>
</tr>
<tr>
<td>180-189.9</td>
<td>83</td>
<td>59</td>
</tr>
<tr>
<td>190-199.9</td>
<td>88</td>
<td>62</td>
</tr>
<tr>
<td>200-209.9</td>
<td>92</td>
<td>66</td>
</tr>
</tbody>
</table>

**Figure 6.1 Hop distances according to height.** Reproduced from Rieman and Manske (2009)

One practice attempt on each leg was undertaken for familiarisation of the procedure whilst avoiding fatigue. Both the dominant leg (as defined as the leg that people would prefer to kick a ball with) and the non-dominant leg were tested in a randomised order (randomisation was undertaken using the Microsoft Excel 2010 randomisation function). After a 10 minute rest, participants were asked to complete the MSLHST again on both legs, in the same order.
The starting position was standardised with the participants standing on one leg with both hands on their iliac crests and eyes facing forwards. Participants were asked to hop to a series of numbered boxes; each with an area of 2.5cm² (see figure 6.2). The task was paced by a metronome (with an auditory cue every one second). On landing on each box, participants were asked to maintain their position for five seconds (counted aloud by the investigator). The balance period was defined as the period prior to jumping, and the period one to five seconds after landing and stabilising the position. The landing period was defined as the one second period immediately after landing, when the participant attempts to stabilise their position.

As described by Riemann et al. (1999a) any error in either a landing or balance phase was counted as a failure. Errors were scored according to the period in the test in which they were committed i.e. three points for an error in a balance period, and 10 points for a landing period error.

The final test score was the sum of the balance and landing error scores. The MSLHST scoring was defined as:

**Balance score.** Three error marks were given for participants committing the following in any balance period:

- Touching the floor with the non-weight bearing limb
- Removing hands from iliac crests
- Non-weight bearing limb touching the weight bearing limb
- Non-weight bearing limb moving into excessive flexion, extension or abduction (this was defined as movement beyond the predetermined stance (>30 degrees of movement); displayed to the participants in a photographic format).

**Landing score.** 10 error marks were given for participants committing the following in any landing period:
• Removing hands from iliac crests
• Foot not covering the numbered square
• Stumbling on landing
• Landing foot not facing forwards with 10 degrees of inversion or eversion

Therefore potential test scores could range from 0 - 130 (0 - 100 for the landing component, and, 0 - 30 for the balance element).

![Diagram of boxes marked out for the MSLHST]

**Figure 6.2 A representation of the boxes marked out for the MSLHST.** Image reproduced from Riemann et al. (1999a)

### 6.4 Statistical Analyses

Statistical analyses were performed using SPSS 20 for Windows (IBM). Two-way random absolute agreement intra-class correlation (ICC 2,1) and 95% confidence intervals were used to assess the intra-rater reliability (Rankin and Stokes, 1998).
Bland Altman plots were presented to show a visual representation of intra-rater reliability (Bland and Altman, 1986). Using more than one measure of reliability has been advised as no one measure is suitable for all reliability studies (Bruton et al., 2000). ICCs give a relative view of reliability, therefore Atkinson and Nevill (1998) strongly advise not to draw conclusions before using methods of examining the absolute reliability.

The minimum difference (MD) required for the score to show a “real” change across measurement sessions was also calculated for both the dominant and non-dominant limbs (Weir, 2005). Figure 6.3 presents the equation; where SEM corresponds to the standard error of measurement.

$$MD = SEM \times 1.96 \times \sqrt{2}$$

Figure 6.3 The equation used to calculate the minimum difference (Weir, 2005)

A paired t-test was used to ascertain if there was a significant difference between the balance ability of the dominant and non-dominant leg (p = <0.05). Regression analyses were undertaken to explore possible relationships between balance ability on the dominant and non-dominant leg, age and time spent training each week. The strength of the correlation coefficients were interpreted as: 0 = zero, 0.1 - 0.3 = weak, 0.4 - 0.6 = moderate, 0.7 - 0.9 = strong and 1 = perfect (Dancey and Reidy, 2004).

The time spent training each week was further explored using t tests to determine the possibility of predicting test performance according to the amount of training undertaken (< or > five hours per week). Such a relationship has been supported by the work of Sundstrup et al. (2010) who showed that lifelong football trained men demonstrated significantly superior balance to age matched untrained men.
6.5 Results

6.5.1 Demographical Data

The demographics of the tested population are presented in table 6.1

<table>
<thead>
<tr>
<th></th>
<th>Age (yrs)</th>
<th>Weight (kg)</th>
<th>Height (cm)</th>
<th>Gender</th>
<th>Dominant Leg</th>
<th>Average Weekly Training Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean</strong></td>
<td>32.8</td>
<td>71.4</td>
<td>174.2</td>
<td>Female = 7</td>
<td>Left = 2</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Male = 8</td>
<td>Right = 13</td>
<td></td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td>9.2</td>
<td>9.5</td>
<td>7.5</td>
<td></td>
<td></td>
<td>4.3</td>
</tr>
<tr>
<td><strong>Range</strong></td>
<td>22-57</td>
<td>53.8-88</td>
<td>162.5-184.5</td>
<td></td>
<td></td>
<td>0.3-14</td>
</tr>
</tbody>
</table>

*Table 6.1 Demographical data* yrs = years; kg = kilograms and cm = centimetres. SD = standard deviation

Table 6.2 presents the dominant and non-dominant leg error scores for each of the participants.
<table>
<thead>
<tr>
<th>Participant Number</th>
<th>Dominant Leg Error Score: Test One</th>
<th>Dominant Leg Error Score: Test Two</th>
<th>Non-Dominant Leg Error Score: Test One</th>
<th>Non-Dominant Leg Error Score: Test Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13</td>
<td>40</td>
<td>23</td>
<td>33</td>
</tr>
<tr>
<td>2</td>
<td>53</td>
<td>63</td>
<td>46</td>
<td>60</td>
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<tr>
<td>3</td>
<td>50</td>
<td>29</td>
<td>53</td>
<td>50</td>
</tr>
<tr>
<td>4</td>
<td>130</td>
<td>130</td>
<td>82</td>
<td>101</td>
</tr>
<tr>
<td>5</td>
<td>59</td>
<td>39</td>
<td>36</td>
<td>43</td>
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<td>6</td>
<td>43</td>
<td>53</td>
<td>36</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>28</td>
<td>48</td>
<td>32</td>
<td>49</td>
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<tr>
<td>8</td>
<td>60</td>
<td>66</td>
<td>61</td>
<td>55</td>
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<td>9</td>
<td>62</td>
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<td>49</td>
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<tr>
<td>10</td>
<td>66</td>
<td>59</td>
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<td>13</td>
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<td>11</td>
<td>42</td>
<td>32</td>
<td>51</td>
<td>58</td>
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<td>67</td>
<td>98</td>
<td>91</td>
<td>117</td>
</tr>
<tr>
<td>13</td>
<td>57</td>
<td>54</td>
<td>77</td>
<td>55</td>
</tr>
<tr>
<td>14</td>
<td>95</td>
<td>79</td>
<td>127</td>
<td>107</td>
</tr>
<tr>
<td>15</td>
<td>110</td>
<td>101</td>
<td>67</td>
<td>94</td>
</tr>
</tbody>
</table>

Table 6.2 Participant’s error scores for the dominant and non-dominant leg

6.5.2 Reliability

Within table 6.3 the ICCs are presented along with the 95% CI. Table 6.4 and 6.5 present the ICCs for the balance and landing scores on each leg.
<table>
<thead>
<tr>
<th></th>
<th>Intraclass Correlation Coefficient</th>
<th>Lower Bounds</th>
<th>Upper Bounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominant Leg</td>
<td>0.85</td>
<td>0.62</td>
<td>0.95</td>
</tr>
<tr>
<td>Non-Dominant Leg</td>
<td>0.85</td>
<td>0.61</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Table 6.3 Intra-rater reliability results. ICC (2,1)

<table>
<thead>
<tr>
<th>Non-Dominant Leg</th>
<th>Intraclass Correlation Coefficient</th>
<th>Lower Bounds</th>
<th>Upper Bounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Landing Score</td>
<td>0.78</td>
<td>0.47</td>
<td>0.92</td>
</tr>
<tr>
<td>Balance Score</td>
<td>0.87</td>
<td>0.64</td>
<td>0.95</td>
</tr>
</tbody>
</table>

Table 6.4 Intra-rater reliability results for the non-dominant leg balance and landing scores. ICC (2.1)
<table>
<thead>
<tr>
<th>Dominant Leg</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraclass Correlation Coefficient</td>
<td>Lower Bounds</td>
</tr>
<tr>
<td>Landing Score</td>
<td>0.72</td>
</tr>
<tr>
<td>Balance Score</td>
<td>0.88</td>
</tr>
</tbody>
</table>

Table 6.5 Intra-rater reliability results for the dominant leg balance and landing scores. ICC (2.1)

6.5.2.1  Bland Altman Plots

Figures 6.4 and 6.5 present visual representations of the intra-rater differences in scores for the dominant and non-dominant legs.

Figure 6.4. Bland Altman plot of the intra-rater differences when the MSLHST is performed on the dominant leg
6.5.2.2 Minimum Difference

The minimum difference (MD) required for the score to show a “real” changes across measurement sessions were calculated as being 44.2 (dominant limb) and 46.8 (non-dominant leg).

6.5.3 Differences between Dominant and Non-Dominant Legs

Paired t-tests revealed no significant differences between performance of the dominant and non-dominant legs in either test (p = >0.05), therefore the scores for the dominant
and non-dominant legs were averaged across the two tests (figure 6.6).

Figure 6.6 The average error scores for the dominant and non-dominant leg

6.5.4 Simple Linear Regression Analyses

There was a significant positive and strong relationship between the scores obtained on the dominant and non-dominant legs; higher scores on one leg were associated with higher scores on the other leg ($R^2=0.49 \ P<0.05$; figure 6.7).
Figure 6.7 A scatterplot showing the linear relationship between the average dominant and non-dominant leg scores on the MSLHST.

There was a significant positive and moderate relationship between the scores obtained on both the dominant / non-dominant legs and the age of the participant. Higher scores (indicating more errors) were associated with older people. The relationship was stronger on the dominant leg (non-dominant leg $R^2 = 0.28$, $P<0.05$, figure 6.7; dominant leg $R^2=0.39$, $P<0.05$, figure 6.8).

Figure 6.8 A scatterplot showing the linear relationship between the average non-dominant leg scores on the MSLHST and age.
Figure 6.9 A scatterplot showing the linear relationship between the average dominant leg scores on the MSLHST and age.

People who trained for more hours per week were associated with lower scores on the MSLHST. This relationship, which was of moderate strength, was significant for the non-dominant leg only ($R^2=0.37$ $P<0.05$).

Figure 6.10 A scatterplot showing the linear relationship between the average non-dominant leg scores on the MSLHST and weekly training hours.
Further analysis using t tests showed a significant difference (p = <0.05) in performance scores between those training more and those training less than five hours per week. This was seen for both the average dominant and non-dominant leg scores.

6.6 Discussion

ICC values can be interpreted as follows; 0.75 and above indicates excellent reliability, 0.4-0.75 is fair to good reliability and <0.4 is seen as poor reliability (Fleiss, 1986). The ICC results for both the dominant and non-dominant leg both demonstrate a mean value of 0.85. Whereas this may be considered as demonstrating excellent intra-rater reliability (Fleiss, 1986), examination of the 95% CI urges more caution. The intervals ranging from 0.62-0.95 for the dominant leg, and, 0.61-0.95 for the non-dominant leg, should be interpreted as showing that the MSLHST has good to excellent intra-rater reliability in a healthy, exercising population.

The varying degrees of reliability shown in tables 6.4 and 6.5 allows a comparison with the findings of Riemann et al. (1999a) on the differences in the landing and balance
score reliability. The current findings show that ICCs range from 0.72-0.88; indicating good to excellent reliability (Fleiss, 1986). In contrast to the findings of Riemann et al. (1999a) reliability is greater with the balance scores. Whilst this may reflect the difference in the prescribed scores given for landing and balance errors, for the purpose of this work the focus upon intra-rater reliability is with the overall MSLHST score. That is the total of the balance and landing scores.

Whilst ICCs were examined to provide a quantitative assessment of reliability in terms of consistency of agreement; Bland Altman plots (Bland and Altman, 1986) were examined as a qualitative method of assessing reliability and determining degree of absolute agreement (Sampat et al., 2006). According to the British Standards Institution (1979) repeatability is accepted for 95% of values with less than 2 standard deviations. Inspection of these plots (figures 6.4 and 6.5) show that the MSLHST intra-rater scores all lay within the 2 standard deviation limits. Considering these findings together with those of Riemann et al. (1999a), it appears that the MSLHST could be a reliable functional outcome measure, and may be considered for inclusion in future clinical trials in a similar population.

According to Thorborg et al. (2011) one may expect to see a difference in balance ability between the dominant/ non-dominant legs. However, the results of paired t-tests demonstrated that there was no significant difference between the dominant and non-dominant limbs (>0.05).

A moderate and significant positive relationship was demonstrated between balance scores and age; higher error scores (indicative of worsening balance) occurred with increasing age when both the dominant and non-dominant legs were assessed. A deterioration of balance with age has been reported previously (Woollacott et al., 1986). Changes include an increased amplitude and speed of postural sway, reduced dynamic balance and greater instability when sensory inputs controlling balance are perturbed or
Many of these studies compared balance ability in younger (<30 years) and older (>60 years) age groups (Singh et al., 2012; Woollacott et al., 1986). It is of note that this measure of dynamic balance appeared able to detect variations in performance with age even within the relatively narrow age band of our sample (22-57 years).

People who trained for longer periods each week had lower scores on the MSLHST (indicating better balance ability). Interestingly, the task used to define the dominant leg was kicking a ball in which the opposite non-dominant leg is balancing, supporting the body weight. The stronger relationship seen between the hours spent training and better performance on the balance scores might be because this leg is used more frequently for balancing activities; especially during asymmetric activities like football that involve phasic movements of the dominant leg.

Predicting performance scores through other variables can be useful in forecasting future performance outcomes. Led by the findings of earlier research (Sundstrup et al., 2010) the number of training hours undertaken each week was explored as a predictor of their MSLHST score; a significant difference (p = <0.05) was shown between participants when grouped in terms of their engagement in training activities. More specifically the results show that it is possible to predict how well a participant will do on the MSLHST by looking at the number of hours that they spend training each week; more than five hours of training per week is a strong indicator that a participant will have a lower error score (indicative of better balance). This is supported by literature in other populations where engagement in sport and physical activities has been shown to be associated with better balance and postural control (Perrin et al., 1999).
6.7 Conclusions

This study demonstrated that the MSLHST has been shown to have good intra-rater reliability in a healthy, active population. The indication of a “real change” in performance scores may help clinicians and researchers using this test in interpreting the findings appropriately. Furthermore simple regression analyses may suggest that predictions may be made as to participants’ MSLHST error scores, based on known factors such as their age and training hours. The latter showing a significant difference (<0.05) in performance between those training more and less than five hours per week. However further work is required to confirm these findings.

In conclusion and concurring with the work of Riemann et al. (1999a), it appears that this test could be an appropriate functional measure of athletic balance to use in a future study with this type of population. Based upon this work the MSLHST was used as an outcome measure in chapter 7.
Chapter Seven A Pilot RCT Investigating the Effects of a Dynamic Elastomeric Fabric Orthosis (DEFO) in Athletes with Pelvic / Groin Pain

7.1 Introduction

Study 1 of this thesis investigated the optimal placement of belts on the pelvic girdle (to improve function and reduce pain) on a sample of athletes with pelvic / groin pain. The results of this study (chapter 3) informed the design of a DEFO.

In study 2 a series of case studies n = 8 was then undertaken in a sample of people with athletic pelvic / groin pain using this DEFO to enable the development of a broad patient profile, by determining “responders” in terms of those whose pain and/or function significantly improved. This has been described in detail in chapter 4. Questionnaire responses suggested the DEFO may have a positive effect upon additional performance related factors, including power and balance (Sawle et al., 2015). Other research into compression style orthoses and shorts has reported mixed findings in terms of performance benefits (Doan et al., 2003; McKim and Taunton, 2001; Kraemer et al., 1998). Therefore, a randomised controlled trial (RCT) is indicated. There are however several factors that need to be determined prior to designing and implementing a full trial such as determining recruitment and dropout rates, potential adverse events and estimating the effect size on which to base a power calculation. Therefore a pilot RCT (Arain et al., 2010) was designed and implemented as described in this current chapter.

7.2 Aims

To conduct a pilot RCT using athletes with pelvic / groin pain to:
Inform the design and test the practicality of procedures for a future definitively powered RCT study (Thabane et al., 2010). In particular to determine the

a. recruitment rate
b. attrition rate
c. presence of adverse events
d. effect size estimate
e. feasibility of using the proposed outcome measures ASLR, squeeze test, broad jump, and the MSLHST
f. effectiveness of the blinding strategy
g. practicality of the proposed protocol

7.3 Sampling and Recruitment Strategy

A convenience sample of volunteers was recruited from UK-based sports clubs over a pre-defined period of one year (January to December 2014). Known clubs (from previous work) and physiotherapists (n= 10) were contacted by telephone and email, and provided with details about the study including eligibility criteria and participant information packs. Potential participants who were interested in finding out more information contacted the investigator (LS) who answered any further questions and, if willing to participate, the investigator arranged a screening session.

Posters were displayed in local clubs/sports centres (n= 8) and Plymouth University (n=5) and visits made by the investigator to aid recruitment. Interested athletes with self-reported pelvic / groin pain were asked to email or telephone the investigator for further information, and to arrange a screening session. This information was provided in the posters.
Monthly adverts were placed in Frontline magazine (the magazine of the Chartered Society of Physiotherapy) and on the DM Orthotics Ltd website, in order to increase awareness of the study and highlight study recruitment procedures. Information about how to contact the investigator was provided in the adverts. Participants were given at least 24 hours from receiving the information pack to providing informed written consent.

7.4 Eligibility Criteria

7.4.1 Inclusion Criteria:

i. Aged 16 years or above (to permit access to academy age athletes). Those under the age of 18 are legally deemed to be children, however following the Gillick case (Cornock, 2007), and the work of Masson (Williams, 2006), it is considered less ethical if their ability to provide consent is not acknowledged. This is dependent upon their ability to understand what they are consenting to, and is in line with the Family Law Reform Act (1969)(The National Archives, 2013) giving those between the ages of 16-18 the right to assent to treatment. Parental consent was also attained for participants under the age of 18.

ii. Self-reported pelvic / groin pain presenting during sport or at rest. Sub-acute (1-3 months duration) and chronic conditions (> 3 months duration) (State of Connecticut Workers' Compensation Commission, 2012) were included.

iii. Pelvic / groin pain as confirmed via a screening procedure (described in detail in chapter 2). When used in isolation these tests have limited reliability, but when used as part of a battery they provide a more conclusive, reliable approach (Stuber, 2007). Positive pain responses were therefore required on at least two or more of these five tests.
7.4.1.1 **Screening Procedure**

See chapter 2 for a detailed account of the screening procedure used.

7.4.2 **Exclusion Criteria:**

See chapter 2 for an explanation of the exclusion criteria.

For the purposes of this study an additional exclusion criteria was self-reported acute pelvic / groin pain; defined as zero to four weeks duration, which may be expected have a short resolution period (Hagglund et al., 2009).

7.5 **Study Design**

A waiting-list control (Elliott and Brown, 2002), researcher blinded (Schulz and Grimes, 2002), pilot RCT was undertaken. The study was approved by the local ethics committee (Faculty of Health and Human Sciences Ethics Committee, Plymouth University; 10/2013. A waiting-list control design was employed for ethical reasons as all participants were selected on the premise that they were suffering from ongoing pain (lasting longer than one month). This design is considered to be a useful method of keeping the control participants engaged with the study (Dempster, 2011).

Random allocation with a minimisation procedure was employed to ensure equal distribution of sub-acute and chronic conditions between the groups. This procedure is more appropriate than stratification for small studies as group allocation considers the participants already enrolled, and creates a better balance (Altman and Bland, 2005). Participants in the intervention group used the DEFO for a four week period. A four week period was chosen to build upon the findings and limitations of the case studies, where some effects were seen over a three week duration. Participants in the control
group served as a waiting-list control for a four week period, before receiving their DEFO by post from the study administrator.

### 7.6 Recruitment Rate

Sources of recruitment, investigator contact with sources, potential participant numbers and actual participant numbers recruited were recorded to inform the design of future studies. The recruitment and attrition rates were reported according to CONSORT Guidelines (Schulz et al., 2010).

### 7.7 Sample Size

Twenty-four athletes were proposed to be randomly assigned to the intervention (n=12) or waiting-list control group (n=12). This is accordance with Julious (2005) and the recommendation of using 12 participants in each group for feasibility/pilot work.

### 7.8 Method

The flow chart shown in figure 7.1 summarises the participants’ route through the pilot RCT.
After obtaining written informed consent, potential participants were screened, and demographic, pelvic/groin pain history and training data were collected and recorded.
Those meeting the eligibility criteria were measured for a DEFO by the investigator. The participants preferred method of contact was noted, and dates for future testing arranged.

One week later (+/- 3 days for flexibility) all participants completed two sets of baseline outcome measures wearing non-Lycra® shorts and loose fitting track pants over the top (these were provided). The use of loose fitting track pants was to standardise what all participants wore and to ensure blinding of the assessor at later dates when the participants in the intervention group could have worn the DEFO (see allocation concealment during outcome measurement below). At this stage loose fitting track pants were used to ensure the consistency of the outcome measurement procedure throughout the study.

At this session each participant was fitted for their DEFO, and given instructions about DEFO use and care. Another physiotherapist’s contact details (Sarah Lay [SL], a clinical specialist in DEFO’s who acted as the study administrator) were provided for any future DEFO queries, and the participants were reminded that they must not talk to the investigator (LS) about the DEFO after this fitting. The DEFO was returned to the factory to allow for any changes required for a bespoke orthosis to fit, and then held by SL until after the randomisation process.

### 7.8.1 Randomisation Procedure

Once the DEFO was ready for use SL randomly allocated the participant to the intervention or waiting-list control group using a web-based system (minim http://www-users.york.ac.uk/~mb55/guide/minim.htm). A minimisation algorithm was used to ensure balance between the groups on the basis of injury chronicity (1-3 months versus > 3 months). Allocation concealment was employed to blind the investigator (LS) to the randomisation process (Wood et al., 2008). SL informed participants by post/ telephone/
email about their group allocation. She posted the diaries to record training, treatment and DEFO usage, and sent the DEFO (with wearing instructions) to the intervention group.

7.8.2 Allocation Concealment during Outcome Measurement

A DEFO may have an orthotic effect, only seen when the orthosis is in situ. Long term use of the DEFO may also result in improvements in the outcome measures even when it is not worn; a “carryover effect” (Matthews et al., 2009). To measure these two potential effects people in the intervention group were assessed both with and without the DEFO. Two assessments were therefore taken at each measurement session. For those in the intervention group, one assessment was completed when wearing the DEFO and another without the DEFO. Participants in the control group were assessed twice without any DEFO. As there is a potential order effect the order of the testing (DEFO versus no-DEFO) was randomised to account for effects such as fatigue or exacerbation of symptoms with testing.

For the two assessments undertaken at each measurement session, participants in the intervention group were randomly assigned to wear their DEFO for either the first or second assessment. SL randomised the wearing of the DEFO, completed paper slips recording this information (and group allocation), and sealed them in opaque envelopes labelled with the participant’s name, study number and the measurement session number. These were sent to the investigator prior to each test date so that she could hand the sealed envelope to the participant at the start of each session. Identical envelopes were also prepared for those in the waiting-list control group; the contents asked these participants to wear sports shorts for both assessment one and two.

During the assessment period the investigator presented the sealed envelope to participants at the start of each assessment session. Participants were asked to confirm
that the envelope that they had been given was sealed and had their name on it and the measurement session (week two, four or six). This was recorded via a digital recorder to confirm that the blinded assessor had not interfered with the envelope / assessment allocation.

7.8.3 Blinding
During testing all participants were asked to wear loose-fitting track pants (which were provided) in order to conceal what they were wearing. At the week two measure photographs were taken of athletes from the torso down at the start of assessment one and then again at the start of assessment two. To determine the effectiveness of the investigator blinding procedure, at the end of the study eight individuals were independently asked to identify whether a participant was wearing a DEFO or not from looking at the photographs. Further, at the end of the measurement sessions at week two, four and six the investigator filled in a blinded assessment form indicating what they felt the participant was wearing.

A criticism regarding the reporting of blinding in studies, is that many studies do not test the effectiveness of their blinding strategy (Schulz and Grimes, 2002). For the purposes of this study if blinding of the investigator was maintained with the methods used then the percentage of correct estimates of the group allocation should be ~50%, indicating that it was performed at chance. The use of Fisher’s Exact Test to assess concealment is explained in section 7.12.6.

7.8.4 Groups
7.8.4.1 Intervention Group
Participants were asked to wear their DEFO for normal training/ sport / physiotherapy input for a four week “intervention” period (week two to week six of the study) and
complete daily diaries to record usage, training, sport and physiotherapy input throughout this period.

7.8.4.2 Waiting-List Control Group

Participants were asked to continue normal training/ performance/ physiotherapy input and record this in their daily diaries for a four week period (week two to week six of the study). After this four week period (week six of the study) the waiting-control group received the DEFO by post from SL. All participants were originally fitted for their DEFO at week one. The DEFO was then held back until SL knew which group they had been allocated to, and when to post them the DEFO.

7.8.5 Timing and Purpose of Assessments

Outcome measures were taken for all participants at week one (baseline), week two, week four and week six. This timing of measures was informed in part by the findings of study 2 (chapter 4), where some participants showed effects immediately after the DEFO was worn. Taking further measures over a four week intervention period was employed to assess the effect of wearing the DEFO over time, and to explore the development of any effects. At each of the sessions the participant was assessed twice (assessment one and assessment two), separated by 10 minutes of rest. The purpose of this was discussed section 7.8.2.

- Participants in the waiting-list control group were tested on all occasions wearing non-Lycra® sport shorts. Shorts with no Lycra® (elastomeric fabric) component were selected to ensure a true control, as other elastomeric fabric shorts and leggings have been reported as having effects upon performance (Kraemer et al., 1998).
Participants in the intervention group were randomly assigned (in line with the randomisation procedure described in section 7.8.1) to wear their DEFO for either assessment one, or assessment two which was after the 10 minute break. They wore non-Lycra® sport shorts for the other assessment.

The measures taken at baseline (week 1), prior to randomisation, when all participants wore non-Lycra® shorts for the two assessments gives an indication of the stability of the outcome measures over time. This was checked using ICCs and Bland Altman plots.

To maximise recruitment all assessment sessions were conducted in the athletes’ clubs/sports centres using portable equipment. The purpose of this was to fit in around the athlete’s schedule, in the most time-efficient way for them i.e. avoid them having to travel. However in order to minimise the effects of external cues such as audience and environmental effects, each athlete was always tested in the same environment with only the investigator present. This was also done to ensure the athlete’s privacy.

7.9 Outcome Measures

Although the squeeze test and ASLR test (explained in chapter 2) were also used in this study, the procedures differed from that used previously. These changes are explained below. The questionnaire used in the series of single cases (chapter 4) and shown in appendix 2 was also used.

7.9.1 Primary Outcome Measure

Squeeze test – Athletes with longstanding groin pain have shown significantly (p = <0.01) lower squeeze test force values than healthy controls (Nevin and Delahunt, 2014).
In the version of the squeeze test used in this pilot RCT, from a supine position (hips and knees at 0°) participants were asked to squeeze their legs together as hard as possible. This position has shown higher force output (Hanna et al., 2010), and minimal variability (Hölmich et al., 2004). Force output was measured using a padded load cell (SGA Applied Weighing, Reading, UK) placed between the medial femoral condyles, an oscilloscope (HPSI 40i handheld pocket scope, Velleman Instruments, Taiwan) and an amplifier (Applied Weighing, Reading, UK). The voltage recorded was subsequently converted into Newtons.

### 7.9.2 Secondary Outcome Measures

#### 7.9.2.1 The ASLR

Previous findings showed that the ASLR test produced low pain scores in a similar sample of athletes (Sawle et al., 2013), therefore the original Mens’ protocol which records difficulty in completing the ASLR (Mens et al., 1999) was also used. Participants were tested as in the screening protocol and asked to rate their pain at completion of the test using a NRS of zero to ten (zero = no pain, ten = worst pain imaginable). Participants were also asked to self-score the difficulty of this task using a rating of zero to five; where zero refers to no difficulty and five is extremely difficult. Both legs were tested.

#### 7.9.2.2 The Broad Jump

The broad jump is a test of power involving multi-joint movements (Markovic et al., 2004) which has excellent test re-test reliability (ICC = 0.97) (Almuzaini and Fleck, 2008). Participants were asked to jump forwards over a mat, taking off from a two-footed stance and using their arms to propel themselves forward, landing with their feet close together. The correct starting and landing positions were displayed photographically to participants, with verbal and written instructions given on the jump
procedure. The distance jumped from the take-off line to the back of the landing foot closest to this line was marked, measured and recorded (Almuzaini and Fleck, 2008). A three metre long safety mat with fabric tape measures affixed vertically along the left hand side was used on which to perform the jumps and their measurement. Standing on the left side of the mat, the investigator marked the rear landing foot position using chalk. A tool made from two attached wooden rods (which could be fixed at a right angle) was employed to ensure the chalked landing point was accurately read off from the tape measure. As per the protocol described by Almuzaini and Fleck (2008) the jump was repeated three times and the furthest distance was recorded as their score.

7.9.2.3 Functional Balance

The MSLHST (investigated in chapter 6) is a functional measure of athletic balance (Riemann et al., 1999a). It has demonstrated good to excellent test re-test reliability in an active population, demonstrating ICC’s (2,1) =0.85 for both the dominant and non-dominant legs, (CI 0.62-0.95 and 0.61-0.95 respectively; chapter six, section 6.5.2).

Participants were asked to jump from a unipedal stance to and from 10 squares placed at distances determined by their height. The test incorporates periods of landing and statically maintaining a unipedal stance, giving participants a balance and landing score for each of the 10 squares. The protocol reported by Riemann et al. (1999a) was used along with the scoring system (chapter 6).

7.9.2.4 The DEFO Questionnaire

Participants were asked to complete the DEFO questionnaire relating to DEFO usage at the end of the study (appendix 2).

For the intervention group the questionnaire was posted out after the final session. The waiting-list control group received the questionnaire four weeks after receiving the
DEFO at the end of their control period. SL posted the questionnaires and received the completed copies to maintain blinding of the assessor.

7.10 Analyses

Results were reported according to CONSORT Guidelines (Schulz et al., 2010). The numbers of participants screened for participation, those deemed eligible or not eligible, numbers randomly assigned to each group, those receiving the intended treatment, and those analysed for the primary outcome were documented.

To establish whether outcome measure scores could be averaged at baseline and for the two assessments per measurement session taken by the waiting-list control group, the test retest reliability was examined where it was not already known. This was undertaken for the ASLR measures as other studies looking at the reliability of this test looked at a different patient group i.e. post-partum patients (Mens et al., 2001). ICC (2,1) and Bland-Altman plots were used; these methods are explained in chapter 6.4.

Fisher’s Exact test was used to assess the effectiveness of the blinding procedures. It is a test used to analyse 2 x 2 contingency tables, and is advised for use with small sample sizes (Freeman and Julious, 2007). Blinding is considered effective if no significant difference is seen between the responses given (incorrect and correct). Level of significance was set at 0.05.

Descriptive statistics were used, as recommended for pilot studies where a powered sample has not been employed (Lancaster et al., 2004). Mean differences between the baseline and week two, week four and week six measures were calculated for each group along with 95% CI’s. Effect sizes were calculated using Cohen’s d standardised
mean difference (see figure 7.2) and interpreted as being small = \geq 0.2 \text{ but } <0.5, 
medium = \geq 0.5 \text{ or large } = \geq 0.8 \text{ (Cohen, 1988).}

\[ d = \frac{M_1 - M_2}{SD_{\text{pooled}}} \]

**Figure 7.2 Formula for calculating effect sizes using Cohen’s d.** Where SD is the standard deviation, and M is the sample mean.

An intention-to-treat approach to the descriptive analysis was employed in order to include data from all participants randomised to a group, ignoring anything that occurs post randomisation (Gupta, 2011). The last measure carried forward technique was used. This was employed in order to deal with any missing data from participants dropping out during the study, and would provide a conservative estimate of their performance had they remained in the study (Streiner and Geddes, 2001).

The free text DEFO questionnaire data was examined in terms of common themes, and the Likert-type items presented as frequencies, medians, and inter quartile ranges (IQR) (Boone and Boone, 2012).

**7.11 Criteria to proceed to full RCT**

In order to determine the feasibility of a full RCT (Thabane et al., 2010), the following criteria was required:

1. The attrition rate is <20% across the length of the study (Bhakta, 2000).

2. The proposed number of participants (n=24) could be recruited over a 12-month period.
7.12 Results

The CONSORT diagram is presented in figure 7.3 and shows the numbers of participants recruited, allocated to each group, and completing the study from January to December 2014. Sixteen athletes were randomly assigned to groups; the attrition rate was zero. The demographical data is presented in table 7.1, and the results of the pain provocation tests used to determine eligibility are presented in appendix 4.

Of the n = 9 allocated to the waiting-list control group eight had chronic pain; one participant was identified as having sub-acute pain during screening, but this became chronic pain (lasting for three months) by the time the baseline measures were taken. In the intervention group all seven participants had chronic pain. The uneven numbers in the two groups are due to the minimisation program which was setup for 12 participants in each group; split evenly across chronic and sub-acute pain.

All participants were training three or more times per week, and were undertaking a mix of aerobic and anaerobic training. Study participants regularly participated in the following sports: Rugby Football Union (n = 2), Football Association (n=5), Tae Kwon Do (n = 2), gymnastics (n =1), running (n= 2), cricket (n =1), gym based classes (n=2), and Gaelic Football (n=1). Competition levels ranged from recreational to professional.
Figure 7.3 The CONSORT diagram showing the flow of participants through the study
<table>
<thead>
<tr>
<th>Demographical Data</th>
<th>Waiting-List Control Group</th>
<th>Intervention Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 9)</td>
<td>(n = 7)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male = 6</td>
<td>Male = 7</td>
</tr>
<tr>
<td>Leg Dominance</td>
<td>Right = 8</td>
<td>Right = 7</td>
</tr>
<tr>
<td>Mean Age in years +/- SD (range)</td>
<td>30.7 +/- 9.3 (22-48)</td>
<td>26 +/- 5.3 (23-36)</td>
</tr>
<tr>
<td>Mean Height in cm +/- SD (range)</td>
<td>179 +/- 6.2 (167-190.5)</td>
<td>180 +/- 8 (164.8-186.5)</td>
</tr>
<tr>
<td>Mean Weight in kg +/- SD (range)</td>
<td>73.2 +/- 15 (56.4-93.4)</td>
<td>80.5 +/- 7.8 (66.2-88.7)</td>
</tr>
</tbody>
</table>

Table 7.1 Demographical information of the study participants

7.12.1 Defining the Site of Pain

The results of the pain provocation tests (appendix 4) showed that all participants displayed bilateral pain responses. When differences in means and SD were examined for the left and right leg ASLR pain scores, minimal differences were seen (mean difference = 0.22; SD = -0.02), making it inappropriate to define one side of the pelvis/groin as the site of pain. Therefore the right and left legs were labelled dominant and non-dominant, as defined by the participant’s preference for kicking a ball.
7.12.2 Reliability

The results of the reliability analyses are shown by way of ICCs (table 7.2) and Bland-Altman plots (figures 7.4 to 7.8).

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>IntraClass Correlation Coefficient (2,1)</th>
<th>95% Confidence Intervals</th>
</tr>
</thead>
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<tr>
<td>Dominant Leg ASLR NRS Score</td>
<td>0.94</td>
<td>0.83-0.98</td>
</tr>
<tr>
<td>Non-Dominant Leg ASLR Mens Score</td>
<td>0.93</td>
<td>0.76-0.98</td>
</tr>
<tr>
<td>Dominant Leg ASLR NRS Score</td>
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<td>0.73-0.96</td>
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<tr>
<td>Non-Dominant Leg ASLR Mens Score</td>
<td>0.96</td>
<td>0.89-0.97</td>
</tr>
</tbody>
</table>

Table 7.2 ICCs for the baseline test retest reliability of ASLR outcome measures.
Figure 7.4 Bland Altman plot of the intra-rater differences for the ASLR pain score (dominant leg)

Figure 7.5 Bland Altman plot of the intra-rater difference for the ASLR test of difficulty (dominant leg)
Figure 7.6 Bland Altman plot of the intra-rater differences for the ASLR pain score (non-dominant leg)

Figure 7.7 Bland Altman plot of the intra-rater differences for the ASLR test of difficulty (non-dominant leg)
After examining the ICCs and Bland Altman plots it was decided that it was appropriate to average all of the the waiting-list control group measures, and the baseline measures for both groups across assessment 1 and 2. This decision was justified by the ASLR ICC values indicating good to excellent reliability and precision (table 7.1). Bland Altman plots also showed that the majority of the difference in test retest values stayed within 2SD (figures 7.4 to 7.7). The decision to average the other outcome measures was based upon their known inter-rater reliability (chapters 2, 6 and 7.9.2.2).

7.12.3 Mean Differences

The mean difference between the baseline and subsequent measurement sessions is shown for each outcome measure by group (intervention and waiting-list control) and intervention group condition (DEFO or sport shorts) in figures 7.8 to 7.15. The waiting-list control group always wore sport shorts, whilst the intervention group were tested with the DEFO and sport shorts. A legend is placed at the start of the figures to explain the format of each figure. Each figure is followed by a brief discussion of what it is showing. Table 7.3 presents the 95% confidence intervals for the mean differences.

For all outcome measures the mean difference was calculated as the intervention period score at week two, four or six minus the baseline (non intervention period) score. The figures present the results as either positive effects (value above zero) or negative effects (values below zero). In order to do this decreases in pain, ASLR difficulty and MSLHST errors from baseline to measurement at weeks two, four or six are shown as positive values.
Figures 7.8 and 7.9 show a consistently bigger mean difference from baseline (indicating improvement in pain and difficulty scores) when the DEFO is worn.
compared to the waiting-list control group, and also when the intervention group wore sports shorts. This is seen across all of the measurement sessions. Whilst it is evident from figure 7.8 that the waiting-list control group shows some improvement in pain scores (i.e. pain decreases), the effect is not as large as in the intervention group. Figure 7.9 highlights that the ASLR is more difficult at week four in the waiting-list control group (mean difference is below zero indicating a negative effect).

![Figure 7.10 Change from baseline in non-dominant leg ASLR pain scores (NRS)](image)

![Figure 7.11 Change from baseline in non-dominant leg ASLR difficulty scores](image)
Figures 7.10 and 7.11 show that wearing the DEFO produced a larger improvement in pain and difficulty scores when undertaking the ASLR across all measurement sessions. Pain and difficulty increased for the waiting-list control group in relation to their baseline score.

![Figure 7.12 Change from baseline in force produced on the squeeze test](image)

In figure 7.12 there is a large improvement in squeeze test force (force output increased) by the end of the intervention period for those wearing the DEFO. This figure shows variability over the measurement sessions as at the first session after baseline, force is detrimentally affected for those in the intervention group. This improves over subsequent sessions when the DEFO is worn; potential explanations for this are discussed in section 7.13.5.
Figure 7.13 Change from baseline in broad jump distance

Figure 7.13 shows that wearing the DEFO improves power (as measured by a field test), and that the mean difference across measurement sessions is consistently larger than both the waiting-list control and when the intervention group is tested wearing sports shorts.

Figure 7.14 Change from baseline in dominant leg MSLHST error scores
Figure 7.15 Change from baseline in non-dominant leg MSLHST error scores

Figure 7.14 and 7.15 show that by the end of the study balance performance improves for both groups on both the dominant and non-dominant legs. For the dominant leg performance is variable across the intervention period for both groups, and is negatively affected in earlier measures for those wearing the DEFO and the control group. Performance is never negatively affected when the intervention group wears sports shorts (figure 7.14). A potential explanation for this is discussed in section 7.13.5.

The non-dominant leg balance performance is positively affected across the intervention period (figure 7.15), but earlier measures for the control group and when the intervention group wear sports shorts show negative effects at week two and four. This variability and the issue of leg dominance are discussed in section 7.13.5.
<table>
<thead>
<tr>
<th>Measures</th>
<th>Week Two</th>
<th>Week Four</th>
<th>Week Six</th>
<th>Week Two</th>
<th>Week Four</th>
<th>Week Six</th>
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<th>Week Six</th>
<th>Week Two</th>
<th>Week Four</th>
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<tr>
<td>Dominant Leg ASLR NRS Score</td>
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<td></td>
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Table 7.3 The mean difference (in bold) and 95% confidence intervals for the mean difference from baseline to assessment week two, four and six for each outcome measure and for each condition.
7.12.4 Effect Sizes

Cohens d effect sizes are shown in table 7.4 and represent the standardised mean difference in the scores of the intervention group compared to the waiting-list control group, at each stage of the study.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Week 6</th>
</tr>
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<tr>
<td></td>
<td>DEFO</td>
<td>Sport Shorts</td>
<td>DEFO</td>
</tr>
<tr>
<td></td>
<td>Effect Size (d)</td>
<td>Effect Size (d)</td>
<td>Effect Size (d)</td>
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<tr>
<td>Dominant Leg ASLR NRS Score</td>
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<td>Dominant Leg ASLR Mens Score</td>
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<td>Non-Dominant Leg ASLR NRS Score</td>
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<tr>
<td>Non-Dominant Leg ASLR Mens Score</td>
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<td>0.2</td>
</tr>
</tbody>
</table>
Table 7.4 The effect sizes (d) for each outcome measure at each stage of the study.

Week six effect sizes represent the effects of the DEFO on completion of the study. NRS refers to the numerical rating scale, and MSLHST refers to the functional balance test.

<table>
<thead>
<tr>
<th></th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
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<td>Squeeze Test Force (N)</td>
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<td>-0.4</td>
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<tr>
<td>Non-Dominant Leg MSLHST Score</td>
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<td>0.8</td>
<td>0.7</td>
<td>0.3</td>
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</tr>
</tbody>
</table>
7.12.5 DEFO Questionnaires

Questionnaires were sent to all study participants (n = 16), of which 11 were completed and returned (intervention group n = 5 (71%); waiting-list control group n = 6 (67%). One questionnaire from the waiting-list control group was later excluded in the analysis as it was returned with no items completed. Hence, 10 questionnaires were analysed; participant responses to the questions are shown in appendix 5.

All 10 participants wore their DEFO for a minimum of four weeks. For the intervention group this was during the intervention period, and for the waiting-list control group this was the four weeks after the study intervention period. At the end of this four week wearing period all participants (five from each group) perceived effects (both positive and negative) upon performance when wearing their DEFO.

The Likert-type items rated the comfort, appearance and likelihood of continuing to wear the DEFO. The responses are shown as frequency graphs in figures 7.16 to 7.18. The median and IQR are also presented. Perceived effects upon performance are presented in figures 7.19 and 7.20.

![Comfort Rating (1-5)](image)

**Figure 7.16 DEFO comfort rating**

Likert-type scale between 1 (not at all) and 5 (very)
Figure 7.17 DEFO aesthetic rating
Likert-type scale between 1 (not at all) and 5 (very)

Figure 7.18 Participant's rating of their likelihood of continuing to wear the DEFO
Likert-type scale between 1 (never) and 5 (absolutely)
Figure 7.19 A frequency chart of performance benefits cited by participants

Figure 7.20 A frequency chart of the negative effects cited by participants
7.12.6 Blinding

Eight individuals were asked to decide whether participants were wearing a DEFO or not by looking at the photographs taken during the week two measurements (n = 32); Forty seven percent of their responses were incorrect. Fisher’s Exact test was used to establish the effectiveness of blinding by analysing the results of this photograph blinding task; the responses were grouped as being either correct or incorrect. This method has been used in other studies to assess the success of the blinding procedure (Zhao et al., 2014). Fisher’s Exact test indicated that there was no significant difference between the groups (p = 0.4). Therefore blinding was effective at the significance level p = ≤ 0.05.

The results of the investigator’s blinding check of effectiveness showed that 50% of their responses were incorrect. The Fisher’s Exact test showed that this result was not significant (p = 1). Therefore the blinding strategy was concluded as being effective.

7.13 Discussion

The aims of this pilot RCT were to determine recruitment rate, attrition rate, the presence of adverse events, effect size estimates, the feasibility of using the proposed outcome measures (ASLR, squeeze test, broad jump, and the MSLHST), the effectiveness of the blinding strategy, and to confirm the practicality of the proposed protocol for the purpose of a future RCT.

7.13.1 Recruitment and Attrition Rates

Out of the 24 participants intended to be recruited for this pilot RCT, only 16 participants were tested. Although the CONSORT diagram (figure 7.3) highlights the problem of ineligibility, it does not show that another 11 participant information packs were requested and received by interested potential participants. Of these potential
participants two reported being unable to proceed due to work commitments, whilst the remaining nine did not respond to further communication. This suggests that the sufficient numbers of participants were available, but that the pre-defined 12 month study duration may have been an issue. Future work needs to consider time constraints, and what could be done to improve the recruitment rate. Recruitment issues are further discussed in section 7.13.7.

Once recruited to the study no participants dropped out which demonstrates that, once enrolled in the study, participants were engaged enough to continue. It could also reflect that the attrition rate was not influenced by uncontrollable factors such as illness and other injuries.

7.13.2 Adverse Effects

No adverse effects were reported to the study administrator who acted as the point of contact for any problems that the participants experienced. Potentially negative effects from wearing the DEFO are explored in section 7.13.5.4. These are discussed in terms of the findings of other literature, and areas which may require further investigation.

7.13.3 Feasibility of Procedures and Outcome Measures

The testing procedures proved to be successful in terms of the logistics, practicality of outcome measures and the successful collection of data. The outcome measures were straightforward to administer and participants reported no difficulties in understanding or completing them. There was no missing data apart from items in one DEFO questionnaire.

The return of 11/16 questionnaires be may the result of a communication lapse. The study administrator reported that many participants never responded to emails (their choice of communication). To attempt to improve the return of questionnaires verbal (e.g. telephone prompts) as well as email communication between the administrator
(SL) and participants may optimise the questionnaire return rate. A full RCT should include a supporting administrator to check that processes are being implemented at the right time and to protect for periods of absence (for example sickness). Creating a limited access shared database for those involved in the administration would ensure smooth monitoring of each participant’s status through the study, and provide a backup for written data (Chan, 2003).

7.13.4 Blinding Effectiveness
The effectiveness of the blinding procedures was explored as described in section 7.8.3. Based upon the blinding results presented in section 7.12.6 the strategy employed proved to be effective. This suggests that this method of blinding (wearing loose fitting track pants over the top of a DEFO or sports shorts) is appropriate for use in future work.

7.13.5 Summary of Outcome Measure Effect Sizes
The results from the pilot RCT show that the DEFO has had varying effects on a range of outcomes in athletes with chronic pelvic / groin pain. In general wearing the DEFO demonstrated moderate to large effects on the clinical measures, and negligible to small effects upon the performance measures. These findings will be discussed below in detail in relation to the clinical and performance measures used.

7.13.5.1 Clinical Measures
By the end of the intervention period (at six week) those allocated to the DEFO intervention were shown to have reduced pain and less difficulty in undertaking the ASLR, and an increase in squeeze test force (d = 0.6 to 1.1) compared to those in the waiting-list control group.
Moderate to large effect sizes (d= 0.5 to 0.8) were also seen on the ASLR measures when the intervention group were tested wearing sports shorts, indicating that there might be a carryover effect from training with the DEFO. Mens’ ASLR test scores showed larger effect sizes (d = 1.1) than pain on ASLR tests (d = 0.6 to 0.9), supporting its appropriateness in this patient group (Mens et al., 2006a), and suggesting that other factors can influence performance difficulty. For example, in other pelvic girdle pain patients increased pelvic mobility has been identified as a factor associated with higher ASLR scores (Mens et al., 1999). This indicates that those with more pelvic joint mobility (laxity) find the ASLR test more difficult. In consensus with the findings in another pelvic pain study (Palsson et al., 2014), higher scores on the ASLR (indicating increased difficulty) were found to correspond to higher pain scores on the test.

Large mean differences between the DEFO and waiting-list control groups (figures 7.8 to 7.12) were observed for each of the clinical outcome measures. Figures 7.10 and 7.11 also show that for the waiting-list control group ASLR pain increased over the duration of the study, and the test became more difficult to perform. This may reflect progression of the condition.

Although in a different patient group, these findings support the results of a previous RCT reporting moderate effect sizes and carryover effects from wearing DEFOs (Elliott et al., 2011). The findings show a more consistent effect on the clinical measures than the previous single case study series undertaken for this thesis (described in detail in chapter 4).

The large effect on squeeze test force (d = 0.8), which is present at both the week four and week six measures, concurs with the effects of external pelvic compression on athletes with adduction-related groin pain (Mens et al., 2006a). The findings from the intervention group wearing sports shorts indicates that this effect was associated only
with wearing the DEFO. This may suggest a splinting effect, and could be explored
with a longer intervention period to establish if a carryover effect becomes evident.
Effects upon the ASLR support previous work in patients with chronic pelvic pain that
found less ASLR difficulty with compression (Beales et al., 2010). There is also support
for the findings of compression orthoses leading to a reduction in pain in athletes with
osteitis pubis (McKim and Taunton, 2001) and improved strength in those with
shoulder instability (Ide, 2003).

7.13.5.2 Performance Measures

Small effect sizes were seen on the broad jump and non-dominant leg MSLHST (d =
0.2 to 0.3 respectively) when the DEFO was worn. A negligible effect was seen on the
dominant leg (d=0.1). No carryover effects were observed.

Other studies into compression shorts and orthoses have shown contradictory findings
in terms of balance and power tests in healthy and patient populations. Force plate
measures of static unipedal balance have been seen to significantly improve (p = <0.05)
in healthy females when well-fitting compression shorts have been worn; effect sizes
were not provided (Michael et al., 2014). The acknowledged limitation in translating
this finding to athletic performance concerns the testing under conditions of visual
occlusion which does not happen in the sporting setting. In contrast Bernhardt and
Anderson (2005) found that compression shorts worn by healthy participants showed no
significant effect (p = 0.9) upon static balance ability when measured using a stork
stand. The effect size was not given by the authors, but was calculated using the data
provided as d = 0.0. In addition to employing visual occlusion this test’s static nature
may not be athletically challenging or adequately responsive for a patient population.
Currently this is not known since no studies of this nature have yet been undertaken.
In an athletic population with pelvic and groin pain, McKim and Taunton (2001) found that athletes with osteitis pubis showed a trend towards improvement in a functional measure of stability; single leg squat (p = 0.08), which equates to a small effect size of d = 0.2. This finding is for the left leg and may indicate improved performance on the leg commonly required to provide stability in order for the dominant leg to perform. Leg dominance is often defined as the leg with which the athlete prefers to kick with (Riemann et al., 1999a), usually the right leg, therefore the left leg takes a more central role in providing stability (Velotta et al., 2011). This may at least partly explain the current study’s finding of a small effect seen in the non-dominant leg MSLHST score (d = 0.3), but minimal improvement seen on the dominant leg (d = 0.1). Due to the presence of bilateral pain in all participants, and the ASLR mean differences and SD showing no difference between right and left leg pain scores (section 7.12.1) the effect of site of pain on these results is not known. Velotta et al. (2011) suggests that leg dominance should be considered in terms of the nature of the task, as the right leg shows dominance in activities requiring manipulation, for example kicking, whereas the left leg is more dominant in postural control activities. The small improvement in the non-dominant or postural control leg, which was supported by subjective reports of increased stability (see questionnaire responses) may indicate that the targeted external pelvic compression led to small but identifiable improvements in the dynamic balance of athletes with pelvic / groin pain.

Field tests of power have also produced mixed findings in healthy athletes. Bernhardt and Anderson (2005) found no significant effect of compression upon vertical jump height, yet customised compression shorts (Doan et al., 2003) have demonstrated significant improvements in countermovement vertical jump height (p = 0.015) but effect size was not given. Previous research has suggested that compression shorts may influence repetitive performance by reducing muscle oscillations (Doan et al., 2003),
influencing proprioception and delivering athlete perceived improvement effects (Kraemer et al., 1998). Kraemer et al. (1998) found that whilst compression shorts did not improve maximal vertical jump power, they did have a significant effect upon repeated jump performance. Mean power output on repeated jumps (n = 10) was significantly improved when compression shorts were worn (Kraemer et al., 1998). Compression leggings have also been shown to improve repeated sprint performance in healthy female athletes. Although there was no effect seen on haemodynamic or physiological measures, an influence upon proprioception was suggested (Born et al., 2014). This may be due to the stimulation of the neuromuscular system. Gluteal muscle kinesio taping has been found to increase explosive power as measured by a field test jump (Mostert-Wentzel et al., 2012).

This pilot RCT concurs with previous findings that wearing compression shorts shows some improvement in power, but contributes new preliminary knowledge that this finding is observed with an athletic population presenting with pelvic / groin pain.

7.13.5.3 Intervention Assessment Points

The effect sizes at different stages of the intervention period i.e. at weeks two and four, show variable results. Mean differences shown in section 7.12.3 indicate that there was consistent improvement over time in many of the outcome measures for those participants wearing the DEFO. Week two improvements in the intervention group whilst wearing control shorts may indicate an immediate carryover effect from wearing the DEFO. It is also possible that this result is the influence of participants being allocated to the intervention group, and behaving accordingly.

However figures 7.12, 13 and 14 indicate that the data varies over time; performance in the DEFO group appears to be detrimentally affected in the earlier assessment sessions before showing improvement at the latter assessments. One possible explanation may be
that athletes underwent a period of adjustment to wearing the DEFO, and that there was variability in how they responded; possibly influenced by their own expectations (Rutherford et al., 2009). It may also be the result of increased discomfort caused by factors including the DEFO, increased training loads and changes in their condition. Early outcome measures may have been influenced by the level of pain at the start of the study, particularly in a population with varying pain mechanisms, and sites of pain (Ficek et al., 2008). Attempts were made to ensure a balance of injury chronicity in both groups by way of a minimisation procedure. However, in view of the chronic nature of all participants, future work may also use a minimisation procedure to allocate participants according to pain levels. Apprehension when undertaking measures for the first time may also have led to a tentative technique, for example squeezing the padded load cell. This may have affected all participants to some extent.

Although the performance measures showed small effect sizes, there may have been a learning effect, indicated by the control group also showing some improvements. Whilst effort was made to limit this by having a familiarisation session at the baseline stage, balance studies have reported learning effects in healthy populations (Riemann et al., 1999a; Hertel et al., 2000). This may also indicate an improvement in their condition.

### 7.13.5.4 DEFO Questionnaire Responses

Increased stability (n =6) and decreased pain (n =5) were the most frequently cited self-reported performance benefits. This perceived reduction in pain appears to be in consensus with the ASLR test scores that show moderate to large effect sizes (d = 0.6 to 1.1), and other studies (McKim and Taunton, 2001). However unlike McKim and Taunton (2001) pain scores were only recorded for the ASLR so the impact that the DEFO may have had on pain during sport has not been quantified. The findings also concur with McKim and Taunton (2001) in the finding that athletes perceived an
improvement in stability from wearing compression shorts. Although not all of the participants rated the impact of the performance effects that they cited, where impact was recorded scores ranged from 1 to 4 for stability and 5 for pain reduction (where 1 = some impact and 5 = significant impact). Self-reports of improved stability and reduced pain support the results of the outcome measures evaluated.

The negative effects that were identified are mostly with regard to the wearability of the DEFO, rather than performance impacts. Prior to a future RCT, the questionnaire should be further refined to optimise its validity. The wearability issues cited in figure 7.20 have now been addressed through the development of a new DEFO pattern, which still maintains the same pelvic girdle configuration of directional compression but enhances comfort and fit. Further details of these modifications are presented in chapter 8.5.

Two self-reported negative impacts upon performance which require further investigation are a possible increase in blood pressure and decrease in vital capacity. In healthy, active females other lower limb compression garments have not been shown to have a significant influence (p = >0.05) upon blood pressure compared to loose fitting garments (Venckunas et al., 2014). Furthermore cardiorespiratory measures, including cardiac output and oxygen uptake, on male and female athletes have not shown to be influenced by lower limb compression during exercise (Born et al., 2014; Sperlich et al., 2011). Nevertheless there is scope for the DEFO used in this study to be explored with regard to impact on these variables.

Aesthetically the DEFO was deemed to be very satisfactory, which is promising for its acceptance by athletes, and concurs with other work into DEFOs suggesting that they are commonly accepted and worn (Yasukawa and Uronis, 2014). This is essential as some orthoses have poor usage rates (Smitham et al., 2012). Comfort ratings were mixed, but 8/10 participants rated the DEFO as being reasonably to very comfortable.
No athlete said that they would not continue to wear the DEFO, with 9/10 participants rating highly the possibility of them continuing to wear the DEFO for sport.

The questionnaire responses have proved to be valuable in complementing the objective measures, suggesting other effects and evaluating the acceptance and usefulness of the DEFO amongst athletes. However, caution should be taken in that the responses were based upon a 62.5% completion rate.

**7.13.6 Pain Provocation Tests**

Participant responses to the five pain provocation tests ranged from two to five positive outcomes. This figure is higher when bilateral pain responses are observed (appendix 4) and concurs with other studies finding bilateral and multiple sites of pain (Mens et al., 2006a).

Out of the 16 participants screened for this study 15 of the participants showed a positive response on Faber’s test. This may suggest the SIJ as a source of pain, but with sensitivity and specificity ranging from 50% to 77% and 16% and 100% respectively (Stuber, 2007), caution should be taken when interpreting the findings from just one test. Other tests showing a high number of positive responses were Gaenslen’s (n =13) and the Squeeze test (n =12). Eight participants exhibited positive responses on all three of these tests, which may identify a multi focal subgroup similar to that discussed by Mens et al. (2006a). Mens et al. (2006a) confirmed that the squeeze test doesn’t just identify adductor pathology, but also found that pain presented in other structures and may exist bilaterally.

As is expected with an inclusion criteria designed to identify athletes with any pelvic/groin pain the pain presentations varied (Ficek et al., 2008). However, there was an evenly matched spread in the number of positive pain responses (two to five) across both groups.
7.13.7 Recruitment

A future study would require an essential change to recruitment strategies. Sources of recruitment proved to be effective in generating interest from prospective participants, but were not effective in recruiting them into the study. This may have been due to the time commitment involved in participating in the study, although every effort was made to explain that measures would be undertaken in locations and at times convenient to participants. As previously discussed, once the participant information pack was received, eleven potential participants were lost for reasons including work commitments. Of those recruited ineligibility and the time/ resources available reduced the number of participants completing the study (refer to figure 7.3). Having co-investigators may have increased this number, and have been more efficient time wise in terms of travelling and accommodating changes in testing dates when multiple participants were being tested. Although this would have cost implications, this is another important change needed for a future study. Other forms of recruitment should also be looked at in future work. It may be necessary to advertise recruitment through other health professionals in order to expand the study profile, and also to look at how poster and web adverts could be made more appealing.

Directing recruitment around Gaelic Football may also have increased participant numbers. Although there is limited literature in this field, which may be due to its amateur status, Gaelic Football has a higher injury rate than Association Football (Murphy et al., 2012). A Gaelic Groin Think Tank reported that over a five year period 24% of academy players suffered a groin injury (Glasgow et al., 2011), higher than the 8-16% cited for footballers (Ekstrand and Hilding, 1999; Werner et al., 2009).
7.13.8 Limitations

Although the intention was to recruit athletes with sub-acute and chronic pain, this was not achieved as none of the athletes had sub-acute pain. Based upon the current findings and the nature of those recruited, the results should be only considered in the context of a future study into chronic athletic pelvic / groin pain. This finding also suggests that it may be more appropriate to focus upon recruiting athletes with chronic pain for future studies.

This was also a partially blinded study which may have been influenced by demand characteristics (Kirk, 1982). In this situation the participants know which group they have been assigned to and may adopt behaviour which they consider the investigator is demanding from them. This may have led to those wearing the DEFO trying hard to improve their performance in order to “please” the investigator. This may explain some of the positive effects seen at week two when the DEFO was initially provided. At week two even when wearing the sport shorts improvements were seen in the intervention group compared to the waiting-list control group (for example ASLR pain and difficulty scores). As the order of testing was randomised this cannot be explained fully by an instantaneous “carry-over effect” as not all participants would have worn the DEFO first. Despite this possible bias double blinding was rejected because the effects of other compression shorts (Kraemer et al., 1998; McKim and Taunton, 2001) would not allow for a true control. Therefore as recommended by Schulz and Grimes (2002), the reporting of blinding procedures was made transparent, and its effectiveness was tested.
7.14 Conclusions and Recommendations

As discussed in section 7.13 the aims of this pilot RCT were achieved in part. Although the intended number and chronicity distribution of athletes was not reached in the set time (Figure 7.3), this may be addressed in the future by employing more focused recruitment drives (for example with Gaelic Football), extending the recruitment period and focusing upon athletes with chronic pain. The criteria of an attrition rate < 20% was achieved. The protocol itself was feasible, and blinding of the investigator was effective (as confirmed in section 7.12.6), but the use of co-investigators would be more time effective and essential for facilitating better recruitment in multiple locations across the UK.

The effect sizes and recruitment/dropout rates suggest that the intervention holds promise as a tool to support the multi-modality approach to pelvic / groin injury management. Based upon these findings and the actions proposed to address recruitment, a future definitively powered RCT appears feasible and is indicated.

Further, based upon the effect size shown for the primary outcome measure (squeeze test force; d = 0.8), it was calculated that 26 participants would be required per group for a future RCT. If effect upon pain is also to be considered then the effect sizes shown for pain on ASLR would increase the group size to 45 (significance level = 0.05; power = 0.8). As all of the patient group studies in this thesis have focused upon both of these outcome measures, it would be justified to view 45 participants per group as the necessary number required for a future study, based on the smaller effect size recorded for the dominant leg pain on ASLR (d = 0.6).
8 Chapter Eight Discussion and Conclusions

The purpose of this chapter is to revisit the aims and objectives of this thesis (presented in chapter 1.13) and highlight what has been learned, how this fits into the current body of literature, and to consider the implications for future work.

8.1 Introduction

Athletic pelvic / groin pain is a complex problem (Ficek et al., 2008) which has been discussed in detail in terms of the diagnostic difficulties, variable injury definitions and the overlap in presentations and causes (chapter 1). The result is that it can easily become a chronic source of pain, often with multiple sites of dysfunction.

Despite the lack of high quality studies underpinning its management (Serner et al., 2015), specifically directed exercise therapy appears to offer the approach with the most consensus, especially as part of a multi-modal programme of therapy (Weir et al., 2011; Hölmich et al., 1999). However, some athletic pelvic/ groin pain remains resistant to improvement, and can be career limiting (Ekçi and Beyzadeoglu, 2014).

Transversely orientated pelvic belts are an orthotic modality, which have been shown to reduce pain and improve function in some athletes with pelvic /groin pain (Mens et al., 2006a) and other pelvic pain patients (Östgaard et al., 1994; Mens et al., 2006b). Despite a lack of consensus in recommending their use (Vleeming et al., 2008; Östgaard, 2007), their role as part of a rehabilitation strategy is still suggested. However, to date transverse belts have only demonstrated to be useful for a sub-group of athletes presenting with a positive ASLR and/or pain on the squeeze test (Mens et al., 2006a; Jansen et al, 2009). The paucity of research into other belt configurations suggests that this warrants investigation.
DEFOs are a more recent advancement in dynamic orthotics (see chapter 1.11). These customised compression-style orthoses are suggested to be able to improve proprioception, provide stability and positively influence pain and function (Attfield et al., 2008; Hylton and Allen, 1997; Ulkar, 2004). They therefore show an overlap with some of the attributes of specifically targeted exercise therapy. However, research in this field is of limited quality and has been directed mostly at neurological patients (Rennie et al., 2000; Gracies et al., 2000; Elliott et al., 2011). Considering this, a DEFO may offer a novel medium for incorporating the effects of pelvic belts into an athletically appropriate form such as shorts, and could provide support for the use of DEFOs as a rehabilitation tool.

8.2 Aim and Objectives

The aim of this thesis was to develop and provide an initial evaluation of a new management tool, the DEFO, to support the multi-modal rehabilitation of athletic pelvic / groin pain.

This was underpinned by the following objectives:

i. To examine the effects of various belt configurations upon pelvic / groin pain and function in athletes (chapter 3)

ii. To use the results from the athletic pelvic belt study to inform the design of a customised DEFO (chapters 4 and 7)

iii. To undertake a preliminary evaluation of the DEFO in terms of its effect upon pelvic / groin pain and function (chapter 4)

iv. To identify potential performance effects, and how these can be measured reliably (chapters 5 and 6)
v. To conduct a pilot RCT examining the effect of this DEFO upon clinical and functional measures of performance, in order to inform a future definitively powered RCT (chapter 7)

vi. To identify where further research is required (chapter 8)

The following discussion evaluates the findings of this thesis and considers them within the wider context of other work.

8.3 Empirical Findings

8.3.1 Direction of Applied Force

A significant effect upon squeeze test force was found with a belt placed below the level of the ASIS and applying 50 N of force, confirming previous findings of the effects of transverse belts (Mens et al., 2006a) and the use of 50N of force (Damen et al., 2002).

New findings from this thesis (chapter 3) indicated that a pelvic belt traversing diagonally towards the site of pain with this same level of force could also significantly improve squeeze test force, and reduce pain on an ipsilateral ASLR. A significant reduction in ASLR pain was also seen with another diagonal belt configuration delivering bilateral pelvic girdle compression. This suggested that other directions of applied force to the pelvic girdle may enhance the effect of a belt, and reinforces the point made by Vleeming et al. (1992) that belt position is more important than the amount of force delivered.

A belt placed caudal to the ASIS has resulted in decreased SIJ laxity (Mens et al., 2006b) and improved ability in completing an ASLR. Further, pregnancy related pelvic pain is related to asymmetric SIJ laxity not overall laxity (Damen et al., 2001). This
suggests that diagonal belt configurations may work to rebalance asymmetric deficiencies in SIJ laxity. Deficiencies causing athletic pelvic/ groin pain have been suggested to be the result of dysfunction in the adductor, pelvis, and abdominal chain (Jansen et al., 2008), and these include oblique slings which may benefit from directional compression addressing any deficits in force closure, and proprioception. The direction of applied force towards the site of pain may enhance force and possibly form closure, by delivering a diagonal compressive force to similarly orientated myofascial slings i.e. anterior and posterior slings. This may provide a more anatomically targeted force than the circumferential force that a transverse belt can apply.

8.3.2 DEFO Effects

Preliminary findings from the single case studies (chapter 4) indicate that the DEFO was associated with improvements in pain and /or function in athletes with pelvic / groin pain, suggesting that the effects seen in the pelvic belt study may have been reproduced. The non-significant findings on the randomisation tests undertaken indicated that caution in interpreting the results is required at a group level, although this may be the result of a type II error associated with insufficient power. However, a developing patient profile of “best responders” to the DEFO has begun to emerge. This profile suggests that the “best responders” to this DEFO are those demonstrating low normalised squeeze test force and /or an asymmetrical ASLR pain profile at baseline. As these characteristics suggest a significant load transfer deficit (Mens et al., 2006a), an explanation may be that the DEFO is contributing to a more efficient load transfer, by addressing instability (figure 1.3). Another explanation may be an improvement in proprioceptive or joint position awareness; a deficit which has been linked to patients with pelvic / groin pain (Mens et al., 2006a; Jansen et al., 2010c).
DEFO questionnaire responses identified possible effects upon performance, self-reported including improvements in balance power and posture, which concurs with research into lower limb compression and healthy athletes (Kraemer et al., 1998; Doan et al., 2003). These subjective findings warranted further exploration to ascertain if there were any measurable effects in this patient population.

Further evaluation of the DEFO (chapter 7) demonstrated a large effect on the primary outcome measure, which was squeeze test force ($d = 0.8$), and moderate to large effect sizes on ASLR pain ($d = 0.6-0.9$) and ASLR difficulty ($d = 1.1-1.1$). This indicates that wearing the DEFO improved performance on those measures over a four week period. This concurs with belt responses seen in some athletes (Mens et al., 2006a; Jansen et al., 2009; Jansen 2010c), and supports the pain decreasing effects of compression shorts on post exercise athletic pelvic pain (McKim and Taunton, 2001). Indications of a negligible to small improvement upon balance ($d = 0.1-0.3$) and a small improvement upon power ($d = 0.2$) relates to previous findings of compression garments in healthy athletes (Kraemer et al., 1998). The significance of this small improvement in performance warrants further investigation in elite athletes, where small performance gains may have large impacts. This is been the discussion of other research into the effects of intervention upon elite athletes (Mostert-Wentzel et al., 2012). In this niche group of athletes very small effects are of huge significance; the classic example is the Olympic 100 metres final where even a one percent improvement in performance can lead to a podium finish (Behm et al., 2004).

8.3.3 Measures of Athletic Performance

The current review of literature (chapter 5) established that there is not a gold standard outcome measure for dynamic balance in athletes (Emery, 2003). The studies were demonstrated to provide a low to moderately high quality of evidence when appraised
using the QAREL tool (Lucas et al., 2010), with a paucity of research into test properties other than reliability. In spite of this the MSLHST was identified as a potentially suitable field test of balance for athletes as it was functional, demonstrated static and dynamic balance components, and the available evidence (which was of moderate quality) showed excellent inter-rater reliability (ICC 2,1 = 0.85) (Riemann et al., 1999a). However, given the relative paucity of research on this measure the decision was made to further explore both its intra-rater reliability and its relationship with factors including training and age. The purpose of this was to provide important additional information to aid in the interpretability of this measure in future trials. In doing so this thesis contributed new findings on the intra-rater reliability of the MSLHST in an active, healthy population (chapter 6) showing ICCs (2,1) of 0.85 with CIs ranging from 0.62-0.95 and 0.61-0.95 for the dominant and non-dominant legs respectively. Further, a significant difference in the MSLHST error scores made was observed between those participants training more or less than five hours per week, providing further evidence of the predictive validity of this measure. Finally the minimum difference to be acknowledged as a real change in performance was calculated as 44.2 (dominant leg) and 46.8 (non-dominant leg) for this healthy, active population. For an improvement in performance this translates as the reduction value (in terms of the error score on the test) needed to demonstrate that a real effect has occurred. The reverse is true for a real decrease in performance. Knowing the minimum difference required can be used in future research studies and rehabilitation settings when ascertaining the true effect of any intervention upon the MSLHST, and to acknowledge lesser changes in scores as noise. Future work is also needed to look at this test in patient populations, and to explore other types of validity and responsiveness.
8.4 Theory and Explanation

The following is an attempt to synthesise the findings of this thesis with the current body of theory and evidence, and evaluate any new contributions to knowledge.

8.4.1 Models of Optimal Function and Stability

Early work has identified form closure (passive), force closure (active), and motor control as the foundation of lumbopelvic stability or effective load transfer (Lee and Vleeming, 1998; Panjabi, 1992b; Snijders et al., 1993); with the added influence of emotion / awareness. This stability reflects the balance between movement and control that can be impaired by too much mobility, a restriction in mobility and insufficient control over mobility. Impairments in instability can present as pain. An interpretation of the relationship between instability and pelvic / groin dysfunction was presented in figure 1.3. This suggests that if deficits in any of these components can cause dysfunction and pain, identifying and addressing the deficit should restore optimal stability and function. However as previously discussed (chapter 1) understanding the focal point(s) for restoring stability is difficult, and is a process which has been underpinned by several conflicting approaches to rehabilitation (Hodges, 1999; Kavcic et al., 2004; Cowan et al., 2004). Reflecting upon the evidence which supports all of these indications, it is possible that each of these approaches have their place in management, and that they all need to incorporated (albeit at different stages) for optimal function to be restored.

It is also appropriate to build upon the findings of Hölmich et al. (1999), Weir et al. (2011) and Serner et al. (2015) on the effectiveness of focused exercise and multimodality (combining exercise with manual therapy) strategies in athletes with long-standing groin pain. From the positive effects observed from the interventions investigated by Hölmich et al. (1999) and Weir et al. (2011), these interventions may
influence components of force closure and motor control. This may also highlight a link between the effects of directed exercise (Hölmich et al., 1999) and the attributes of external pelvic compression which have also been linked to positively affecting motor responses and force closure (Arumugam et al., 2012).

8.4.2 Potential Mechanisms of a DEFO

External pelvic compression (mechanical, manual or belt) has been shown to alter pain, kinematics, ligament laxity and muscle recruitment strategies by influencing neuromotor control, form closure and force closure (Arumugam et al., 2012; Damen et al., 2002; Beales et al., 2010; Mens et al., 2006a). Improvements seen in clinical tests (ASLR and squeeze test) and the reduction in athletic groin pain following the application of a pelvic belt, may address a deficit in stability by influencing the active and passive structures, and thus kinematic control. A pseudo-fascial effect of compression (Arumugam et al., 2012) and proprioceptive influences (Jansen et al., 2010c) have also been suggested, reiterating the complexity of stability and providing credence for the use of a multimodality rehabilitation approach.

It is also possible that patient responses to compression may help to define their underlying deficit. Some patients with pelvic/ groin pain respond well to belt compression, as demonstrated with improvement in their squeeze test and ASLR response when wearing a belt (Mens et al., 1999; Mens et al., 2006a; Jansen et al., 2009; Jansen et al 2010a,c). This suggests that their cause of pain may vary mechanistically from those who do not respond to belt compression, and may explain the variable responses seen in chapter 4. Further, the use of tests such as the ASLR and squeeze test could help identify the “best responders” to targeted compression. Understanding any differences between “responders” and “non–responders” to this type of compression will help to develop and refine interventions strategies for both groups. In future this
may lead to more targeted interventions based on people’s unique response to clinical tests. This has important implications with regards to cost effectiveness, as other treatment strategies may be more economical and effective for some subgroups of patients.

Suggestion of belts acting to self-brace the SIJ comes from work showing decreased EMG activity in muscles such as OI in healthy controls and biomechanical models (Snijders et al., 1998; Hu et al., 2010). However, the finding that SIJ pain patients show variation in their EMG responses was discussed in chapter 1.9, theorising that these responses could classify patients as those lacking force closure and motor control, and those lacking form closure (Beales et al., 2010). Other patient groups (non-specific chronic low back pain) have also shown subgroup differences. Whilst this patient group show similar deficiencies in neutral spine repositioning, they can be further classified into subgroups by their directional specific deficits (Sheeran et al., 2012).

In terms of SIJ pain patients the finding of abnormal motor responses with the application of compression indicated that the situation was complex (Beales et al., 2009, 2010; O’Sullivan et al., 2002), and suggests that compression may work on a symptomatic level, and affect passive structures (Brizzolara et al., 2015). Again this reiterates the need for a multifaceted approach to rehabilitation. Other work suggests that directional compression may be more effective than general compression (Chaudhari et al., 2014). Compression shorts applying directional compression (targeting the anterior and posterior muscle slings; see figure 1.1) have been found to reduce adductor muscle activity in the stance limb. This finding was in healthy athletes but demonstrates a significant difference between standard and directional compression shorts when athletes engaged in run-to-cut drills (Chaudhari et al., 2014). The implication is that directional compression may reduce the risk of pelvic/ groin injuries,
by reducing the adductor forces acting upon weaker abdominal muscles (Hackney, 1993). Chapter 1 also highlights that there are other causes of pelvic / groin pain.

Future work exploring the mechanisms of a DEFO could build on previous techniques. Mens et al. (2006b) for example, vibrated the sacrum and measured the transmission of vibration through the SIJ using Doppler Imaging of Vibrations (DIV). By applying small windows in the DEFO to allow for the placement of the ultrasound probe this method could be adopted to explore their impact on SIJ laxity. EMG activity in pelvic muscles could also be recorded with / without the DEFO during tests that require load transmission through the SIJ, such as single leg stance. Surface electrodes could record from superficial muscles such as the gluteus medius whilst fine wire electrodes would be required for deeper muscles such as transversus abdominis (TrA). These electrodes would need to be inserted under ultrasound guidance (Marsden et al., 2013) but once in situ are quite stable and allow the participant to undertake dynamic activities. Here changes in signal amplitude and timing could be assessed with standard tasks (for example raising and lowering a limb; step initiation) with and without the DEFO whilst the fine wire electrodes stay in place.

DEFOs may also have effects on postural stability, balance and proprioception but these claims are not well quantified, and are often just theorised (Hylton and Allen, 1997). However, the literature on athletic compression garments has reported significant effects upon balance, power and recovery markers (Kraemer et al., 1998; Doan et al., 2003), and these may share similarities to DEFOs, especially where targeted compression and customised garments are used. Findings of significant improvements in hip joint position sense, a reduction in muscle oscillation and force attenuation, underpin suggested mechanisms for the effects of compression garments, but much of this research has been on healthy athletes (Doan et al., 2003).
In the future, as well as looking at the effects of a DEFO on functions such as hip joint position sense in athletes with pelvic/groin pain it could be possible to explore the impact of a DEFO on the proprioceptive control of standing balance. Here, postural responses could be elicited using muscle vibration at around 90 Hz that activates muscle spindles. In standing muscle vibration leads to stereotyped postural responses (Popov et al., 1999). The central nervous system interprets the vibratory stimulus and the ensuing muscle spindle activation as a lengthening of that muscle and elicits a postural response automatically in the opposite direction. Vibrating the ankle plantar flexors, for example, leads to a backwards sway. If a DEFO were to increase proprioceptive input it could alter the size of the response to a stereotyped muscle vibration of the hip abductors, for example, that when vibrated lead to a stereotyped lateral sway (Popov et al., 1999).

One could also explore the mechanisms of action of a DEFO by examining other patient groups and looking at its actions on other body parts. People with a proximal myopathy (for example limb girdle muscular dystrophy) have signs of proximal muscle weakness but intact proprioceptive input and normal bony alignment and thus form closure (Ribot-Ciscar et al., 2004). In contrast S1 nerve root lesions result in, amongst other weaknesses, proximal weakness (for example the hip abductors) and proprioceptive / cutaneous loss in the S1 territory (Katirji, 2013). Exploring the differential effects of the DEFO in these two patient populations would provide insight into the effects of the DEFO on force closure, and the relative importance of proprioceptive / cutaneous input in mediating these responses. In contrast assessing the effects of a DEFO on people following pelvic girdle fractures that primarily affect form closure could provide some insight into the effects of the DEFO on this source of instability.

Finally, a DEFO may have common actions regardless of where it is sited. One difficulty with the pelvis region is that some peripheral nerves controlling the motor and
sensory nerves are deep and difficult to stimulate in isolation. Being able to access these could help in the investigation of the mechanisms of action. Other body parts such as the ankle are supplied by nerves that are more accessible. In these cases the mechanisms underlying any effects of a DEFO could be explored using selective nerve blocks of motor and/or cutaneous nerves (for example the sural nerve) or alternatively by cooling and warming the limb that in the initial stages preferentially affects the 1a afferents carrying proprioceptive information (Kitchen, 2008).

In summary, from a broad perspective the DEFO developed through this thesis could be suggested as acting to enhance pelvic stability. This concurs with the theoretical models (Lee and Vleeming, 1998; Panjabi, 1992b) and other experimental findings (Mens et al., 2006a). However, to date we are not able to explain individual responses to the DEFO or underlying mechanisms of action. Future work could allow us to understand the underlying mechanisms of action and use this to predict who would benefit from treatment, thereby enabling further development of other interventions to complement the action of the DEFO.

### 8.5 Limitations

Several limitations of the work discussed in this thesis have been identified. These are outlined below as participants, pain mechanisms, pain provocation tests, outcome measures, blinding and the literature review, and should be considered in view of the findings.

#### 8.5.1 Participants

Athletes were recruited under a broad description of self-reported pelvic / groin pain. They were screened using a battery of tests designed to confirm pain in multiple structures including the SIJ, symphysis pubis and adductors. This decision was
informed by research reporting multiple sites of pain and injury, bilateral presentations and diagnostic difficulties. The heterogeneous nature of this population makes comparisons to other research using specific patient groups difficult. However, Jansen et al., (2008) has argued that a strong case cannot be made for diagnosing adductor tendinopathy, osteitis pubis or abdominal wall weakness as single causes for long-standing groin pain, and therefore other research may also have used similarly heterogeneous populations. Other work has acknowledged this finding (Mens et al., 2006a).

For the purposes of sampling a more homogeneous population, future work may consider selecting the patient group according to defined test responses. An example could be a painful response to the squeeze test along with a positive response to the ASLR. It may also be appropriate to focus upon athletes of similar skill levels. The population studied in this thesis used athletes from recreational to Olympic level; sampling only professional athletes may refine some of the effects reported, although is likely to hinder recruitment.

8.5.2 Pain Mechanisms

The pelvic belt study began with the intention of recruiting athlete participants with pelvic / groin pain of any duration. Initial thoughts were that the instant effect of belt compression was the focus. However, it should be considered that mechanisms of action associated with acute, sub-acute and chronic conditions may vary. Therefore athletes with differing pain presentations may have responded quite differently.

From the single case studies onwards recruitment became dominated by the number of participants with chronic conditions, and subsequently led to a focused recruitment drive for sub-acute and chronic pain participants. However, as athletes in both the single case studies and the pilot RCT all had chronic pain, this may indicate that these studies
only provide evidence of effect in supporting the management of chronic conditions.
Future work should therefore explore the effects of the DEFO in people with acute and
sub-acute pelvic/groin pain. However, this could pose significant logistical issues
related to the delays associated with measuring and manufacturing a customised DEFO
(typically seven days). These delays will need to be addressed if the DEFO is going to
be suitable for professional sports people with an acute injury given the pressure on
them returning to sport.

8.5.3 Pain Provocation Tests
Justification for establishing the inclusion criteria at a minimum of two out of five
screening tests was provided in Chapter 4. However, with the recruitment focus
changing to chronic pain, it may have been appropriate to include a “pain on palpation”
screening test and extend the minimum inclusion criteria to three out of six tests.
Palpation of the proximal insertion of the adductors has been used to identify athletes
with long-standing adduction related pain (Weir et al., 2011), along with palpation of
the long dorsal ligament for SIJ pain (Vleeming et al., 2008) and symphysis pubis
palpation in pelvic girdle pain patients (Vleeming et al., 2008). An algometer could be
used to standardise the applied force during palpation. A palpation test warrants
consideration, but must be considered alongside its ordering in the screening procedure
and the need to minimise irritability.

8.5.4 Field Tests
Field tests of power and balance were chosen in the pilot RCT in order to use a portable
testing procedure which would allow testing to be conducted in locations convenient to
each athlete. Despite both the MSLHST and the broad jump demonstrating good to
excellent test retest and inter rater reliability (chapters 6 and 7), a limitation is that these
tests have limited data investigating their validity and responsiveness. Responsiveness is
particularly important to know in order to use these tests to evaluate the effectiveness of an intervention. Further work is needed to extend our understanding of the psychometric and clinimetric properties of these tests.

8.5.5 Blinding
A limitation of the single case studies was that no attempts at blinding were made, and therefore bias may have been apparent at both investigator and participant ends (Karanicolas et al., 2010). This was acknowledged in chapter 4 where it was highlighted that the purpose of the single case studies was to provide a preliminary exploration and evaluation of the DEFO design to establish if there was the potential to continue to explore the DEFO as a management tool. Subsequently, once it was established that further work was warranted, investigator blinding was employed in the pilot RCT; the decision not to blind the participants was explained in chapter 7. In light of this, the single case studies data should be considered with some caution.

8.5.6 Literature Review
A systematic approach to searching and appraising the literature on athletic balance measures was employed (chapter 5), but a limitation is that the process was undertaken by one person. Therefore decisions on study eligibility, the use of QAREL in assessing quality (Lucas et al., 2010), and the interpretation of the findings were completed without consensus. Consequently the potential for bias cannot be ignored. This may be reflected in the selection of the MSLHST for the pilot RCT.

8.5.7 Outcome Measures
The ASLR was used as a pain test in the pelvic belt study and single case studies, instead of as a test of difficulty in load transfer (Mens et al., 2006a; Mens et al., 1999). The reasons for doing this and the subsequent limitations were discussed in chapters 4 and 7. The pilot RCT used both the pain response and difficulty in completing the
ASLR in order to address previous limitations (explained in chapter 7) and to confirm the relationship between pain and difficulty. Although higher pain scores corresponded with scores indicating increased difficulty (chapter 7), and this confirmed other author’s findings of this relationship (Palsson et al., 2014), a larger effect size was seen in the “difficulty” (Mens et al., 1999) version of this test, indicating that the DEFO reduced difficulty. This suggests that using this version may have demonstrated different findings in earlier studies (chapters 3 and 4); possibly a bigger effect if consistent with the pilot RCT findings, although different pain presentations may also explain the findings. Future work should include the ASLR as a test of difficulty, and may be useful for identifying those who improve with compression (Jansen et al., 2009).

The squeeze test has also been identified as a useful predictor of those who respond to compression (Mens et al., 2006a; Jansen et al., 2009; Jansen et al., 2010a,c) and was selected as the primary outcome measure for the three patient population studies in this thesis (chapters 3, 4 and 7). The position in which the squeeze test can be measured varies (Verrall et al., 2005; Hanna et al., 2010), with some positions being more stressful and eliciting higher force production. Findings from the earlier studies (chapters 3 and 4) showing low pain scores suggested that a more stressful test position was indicated; therefore a new position was used for the pilot RCT. The position of hips and knees at zero degrees, and the load cell placed between the medial femoral condyles has shown higher force values in healthy athletes used to provide normative data for groin injury patients (Hanna et al., 2010), and this along with its reliability dictated selection. However, it is acknowledged that there are mixed findings in that other research has reported increased muscle activity and higher pressures (using a sphygmomanometer) with the test performed with hips at 45 degrees (Delahunt et al., 2011). Feedback from several athletes in the pilot RCT were that they found the hips at zero degrees was more stressful (experienced more pain) than at 45 degrees (which was
the pain provocation test position). Future work should consider measuring pain as well as force production on the squeeze test and systematically assess the effects of a change of hip angle on the reported pain and how this varies with a person’s clinical presentation.

8.6 Contribution to Knowledge and Implications

There are a number of implications of this thesis. Firstly the findings support previous work on the beneficial effects of pelvic belts in athletes with pelvic / groin pain and forces used. Secondly, this work has also suggested that other belt configurations may demonstrate better effects; particularly diagonal configurations (chapter 3). This is a novel finding as other pelvic belt configurations (directions of applied force) have not been previously explored. These effects are not limited to the use of belts (Arumugam et al., 2012), and the findings of chapters 4 and 7 suggest that clinicians may wish to consider other methods of delivering external pelvic compression in patients with chronic pelvic/ groin pain, such as the DEFO. The development of a DEFO for athletic pelvic / groin pain has been another important tangible from this thesis work. Work begun to explore the effect of this DEFO has laid down the groundwork for subsequent research in this field. This new knowledge may also be transferable for the use of the current DEFO and the development of similar DEFOs in other patient groups. Although the current work has been on the development and use of a DEFO for a long-standing condition, the technology exists to create similar orthoses for acute conditions. This may be particularly relevant for sporting injuries where the use of ankle orthoses and taping is already prevalent. For practical reasons, including the time taken to measure and manufacture, a non-customised “off the shelf” orthotic may be more appropriate for injuries of a more acute nature.
DEFOs offer a customised and clinically prescribed tool and therefore can be developed, modified and used to meet individual patient requirements. The use of a DEFO may also be appropriate for other patient groups experiencing pelvic / groin pain, for example those suffering from pain during or after pregnancy. This group have already demonstrated improvements from wearing transverse pelvic belts (Mens et al., 2006b) and other orthoses have been shown to help with the management of pregnancy related low back pain (Kalus et al., 2008). The latter study indicated that whilst pain levels significantly reduced in those allocated the orthotic and in those using a control (Tubigrip®), there was no significant difference between the two groups (Kalus et al., 2008). This suggests that any form of pelvic compression may have an influence on symptoms (Arumugam et al., 2012), but that exploring bespoke options, such as DEFOs, may offer further benefits as seen with diagonal belt configurations and athletes.

It may also be interesting to explore the use of the athletic DEFO with pelvic / groin pain associated with healed pelvic fractures or lower limb amputation. The effects upon pain and function, and athlete perceptions of improved stability, suggests that these patient groups may potentially benefit from targeted pelvic girdle compression. Further a study on the use of pelvic compression belts in athletes with hamstring injury has already been undertaken to establish if belts can decrease muscle activity during unipedal stance (Arumugam et al., 2015). This is based upon previous findings of increased gluteus maximus and biceps femoris activity in people with injured hamstrings, with the latter also being found in SIJ pain patients (Bussey and Milosavljevic, 2015). However, the findings suggested that a belt (although the effect sizes were small) actually increased muscle activity (Arumugam et al., 2015). As hamstring activity has shown the reverse effect (i.e. a decrease in EMG amplitude) in SIJ pain patients (Jung et al., 2013), it would be of interest to explore the effect of the
DEFO (shorts) and its diagonal force configuration upon hamstring activity. Findings of directional compression shorts reducing adductor activity (Chaudhari et al., 2014) suggest that this style of compression is more effective than general compression.

Based on the feedback from the pilot RCT questionnaire indicating that athlete’s accepted the use of a DEFO (chapter 7), it may be appropriate to consider the use of DEFOs for supporting the management of other sports injuries. It would be valuable to understand the mechanisms by which DEFOs work, and to clinically reason their provision. This is discussed in section 8.8.

This thesis has also provided some evidence to demonstrate that the DEFO can be effective in reducing pain and improving function in some athletes suffering from resistant to therapy, chronic pelvic/ groin pain. When considering those candidates who are most likely to benefit from this modality, the data suggests that this should be reasoned in view of a patient’s response to pelvic compression (belt or manual) on the ASLR and squeeze test (Mens et al., 2006a, Jansen et al., 2009; Jansen et al., 2010a,c), with additional clinical consideration given to contraindications and cautions.

It has been suggested that pelvic belts propagate abnormal patterns (Beales et al., 2010). The influence of the DEFO upon motor control is not yet known, but there is a possibility that wearing the DEFO over the longer term may lead to muscle atrophy and altered motor control patterns, since it provides external support and compression, Future work should therefore explore the impact of long term usage on these factors. As discussed earlier many of the muscles that participate in force closure and mediate motor control in the pelvic area are deep (for example TrA and OI). Fine wire EMG electrodes could be used to record changes in the timing of muscle activity during functional tasks, as has been performed in people with low back and groin pain (Hodges and Richardson, 1996; Cowan et al., 2004). However, this may not be an ideal way of
providing an estimate of muscle atrophy due to the variability in electrode resistance and placement with serial insertions of fine wires over time. Instead measures of muscle thickness at rest and with a standard contraction using ultrasound could be used. Ultrasound also has the advantage of being non-invasive. It would also be important to explore whether using the DEFO as part of a clinical rehabilitation programme mitigates any potentially deleterious changes such as muscle atrophy and enhances the beneficial effects on pain relief and function.

This thesis has also contributed new knowledge on the functional, symptomatic and performance effects of prolonged pelvic compression by wearing the DEFO. To date, previous literature has only reported on the instantaneous effects. Early evaluation of this DEFO through the use of participant questionnaires also suggests that the DEFO, as an adjunct to therapy, was readily accepted by athletes in terms of aesthetics, durability and use during training / sport (chapter 7).

In terms of functional balance measures this work has provided evidence to demonstrate the intra-rater reliability of the MSLHST. Further it has produced scores for what can be considered to be a real change in performance on this test (chapter 6), which has important implications for pre and post season screening of athletes. Balance is a common screening tool to identify a pre injury baseline to inform post injury rehabilitation (Emery, 2003). This data identifies the MSLHST as a very repeatable test for a clinician to use, and highlights where a change in score is significant enough to warrant intervention or monitoring.

8.7 Future Work

Despite the desired recruitment rate not being met in the pilot RCT (chapter 7), the effect sizes for the clinical measures hold promise that this intervention may be
effective. They indicate that efforts made to overcome recruitment difficulties are warranted, and that a definitively powered RCT is appropriate. Recruitment difficulties may be overcome by use of focused recruitment drives, for example in known high groin injury sports such as Gaelic Football (primarily based in Ireland). It would also be appropriate to extend the recruitment and testing period to accommodate various training and playing schedules.

The feasibility of the procedures used in the pilot RCT demonstrated that they could be employed with minor revisions needed. This should include improvements in the communication between the participants and the administrator to facilitate a better questionnaire return rate (e.g. telephone contact to replace or supplement email communication), the inclusion of a palpation screening test (to improve the diagnostic criteria used), and recording both pain and force on the squeeze test, as Jansen (2010; unpublished thesis) identified this as important in terms of those responding to pelvic belts.

Discussion through this chapter has already suggested the need for work to explore the mechanistic nature of this DEFO. Understanding if and why there are differences in patient responses to the DEFO, as have been reported with manual compression (Beales et al., 2010), would help facilitate a better process for clinically reasoning its use. Exploring the idea that DEFOs may influence proprioceptive awareness by stimulating mechanoreceptors and thus improve joint position sense (Ulkar, 2004) is further research which could potentially improve the understanding of this DEFO. Joint positioning deficits recorded in chronic low back pain patients have been shown to exist regardless of the cause of pain (Georgy, 2011). Therefore understanding the awareness of proprioceptive deficits in athletes with pelvic /groin pain may contribute to a better
understanding of the various presentations within this patient group, and where the rehabilitation focus needs to be.

There is also scope to explore the use of this DEFO in the prevention of pelvic / groin injury. Based on the findings of decreased adductor and biceps femoris activity with compression (Jung et al., 2013; Chaudhari et al., 2014) in both healthy and pelvic pain groups, and the risks associated with increased and asymmetric activation, there may be a preventive role for the DEFO. As previous pelvic / groin injury is a risk factor for further injury (Whittaker et al., 2015), this group of athletes would be appropriate to investigate.

Future work may also consider the thermal effects of the DEFO upon performance. Studies have reported that compared to control shorts compression shorts can significantly increase skin temperature during exercise (~1 degree centigrade) (Venckunas et al., 2014), and that there is a relationship between increased skin temperature and increased muscle temperature (Doan et al., 2003). It has also been shown that during short duration exercise neuromuscular function can be affected by muscle temperature; functions such as nerve conduction velocity improving with higher temperatures. Improved performance has been also observed on vertical jump tests of power after the lower limbs have been heated (Racinais and Oksa, 2010). This suggests that it may be appropriate to test the effects of the DEFO after warm up exercise, as this may show different effects to tests undertaken immediately after donning the DEFO.

### 8.8 Conclusions

This thesis has sought to systematically explore the potential use of a DEFO in the management of athletic pelvic / groin pain. This has been achieved in a step-wise manner by investigating the direction of force on the pelvic girdle in order to assess the
effects upon athletes with pelvic / groin pain, exploring a gap in the literature, and then developing and evaluating a novel management tool.

Findings indicated that diagonal pelvic belt configurations provide further benefits to athletic pelvic / groin pain and function compared with transverse belts. The use of this new information informed the development of a customised DEFO in the form of shorts, which subsequently gave a preliminary indication of effectiveness in reducing pain and improving function in some athletes, and a developing profile of the “best responders.” The final study provided some preliminary evidence to demonstrate moderate to large improvement effects on the clinical tests (large on the primary outcome measure; the squeeze test), when the DEFO was worn; and small improvement effects upon performance measures (balance and power).

It is suggested that this DEFO may be appropriate in supporting the management of chronic athletic pelvic / groin pain. Further work on this DEFO should look to undertake a definitively powered RCT in this patient group, and explore its mechanistic attributes.
9 Appendices

Appendix 1. Ethical approval letters

7th January 2009

CONFIDENTIAL
Ms Leanne Sawle
DM Orthotics,
Tescan Units
Pool Industrial Estate
Redruth
Cornwall
TR15 3RX

Dear Leanne Sawle

Application for Approval by Faculty Research Ethics Committee

Title: ‘Developing a lycra orthoses to accelerate return to sport after lumbo-pelvic pain’.

Thank you for sending us the revision to your ethics approval as requested. I am pleased to inform you that the Committee has now granted approval to you to conduct this research.

Please note that this approval is for three years, after which you will be required to seek extension of existing approval.

Please note that should any MAJOR changes to your research design occur which effect the ethics of procedures involved you must inform the Committee. Please contact Penny Beech on (01752) 233795 or by email pbeech@plymouth.ac.uk

Yours sincerely

Professor Michael Sheppard PhD
Chair - Faculty of Health & Social Work
Research Ethics Committee
10th March 2009

CONFIDENTIAL
Dr Jenny Freeman
Reader (Physiotherapy and Rehabilitation)
University of Plymouth
School of Health Professions
Peninsula Allied Health Centre
Room FF21
Derriford Road
Plymouth
PL6 9BH

Dear Jenny Freeman

Application for Approval by Faculty Research Ethics Committee

Title: ‘Developing a lycra orthoses to accelerate return to sport after lumbo-pelvic pain’.

Thank you for sending us the request for amendment to the recently approved ethics application for the above study (Leanne Sawle, Professor Jonathan Marsden and Dr Jenny Freeman). I am pleased to inform you that the Committee has granted approval to you to implement this amendment.

Please note that this approval is for three years, after which you will be required to seek extension of existing approval.

Please note that should any MAJOR changes to your research design occur which effect the ethics of procedures involved you must inform the Committee. Please contact Penny Beech on (01752) 233795 or by email pbeech@plymouth.ac.uk

Yours sincerely

Professor Michael Sheppard PhD
Chair - Faculty of Health & Social Work
Research Ethics Committee
Dear Leanne

Reference Number: 12/13-75

Application Title: Intra and inter-rater Reliability and the Multiple Single-Leg Hop-Stabilisation Test.

I am pleased to inform you that the Committee has granted approval to you to conduct this research.

Please note that this approval is for three years, after which you will be required to seek extension of existing approval.

Please note that should any MAJOR changes to your research design occur which effect the ethics of procedures involved you must inform the Committee. Please contact Claire Butcher on (01752) 585337 or by email claire.butcher@plymouth.ac.uk

Yours sincerely

Professor Michael Sheppard, PhD, AcSS
Chair, Faculty Research Ethics Committee
4th October 2013

CONFIDENTIAL

Leanne Sawle
DM Orthotics Ltd
Unit 2 Cardrew way
Cardrew Industrial Estate
Redruth

Dear Leanne

Application for Approval by Faculty Research Ethics Committee

Reference Number: 12/13-156

Application Title: A pilot RCT to investigate the effects of a dynamic elastomeric fabric orthosis (DEFO) in athletes with pelvic pain, across selected clinical and performance measures

I am pleased to inform you that the Committee has granted approval to you to conduct this research.

Please note that this approval is for three years, after which you will be required to seek extension of existing approval.

Please note that should any MAJOR changes to your research design occur which effect the ethics of procedures involved you must inform the Committee. Please contact Sarah Jones by email sarah.c.jones@plymouth.ac.uk

Yours sincerely

Professor Michael Sheppard, PhD, AcSS,
Chair, Research Ethics Committee -
Faculty of Health & Human Sciences and
Peninsula Schools of Medicine & Dentistry
Appendix 2. The DEFO Questionnaire

Please complete the following questions by ticking the appropriate box, and adding further information if necessary

Participant Number: Date:

Did you wear the DEFO (shorts)?

Yes ☐

No ☐

If YES, please continue with this questionnaire.

If NO, please comment as to why you didn’t wear them at the end of the questionnaire.

1. How comfortable did you find wearing the DEFO for sport /physical activity?

☐ 1 2 3 4 5
NOT AT ALL REASONABLY VERY

If you ticked box 1 or 2, please explain why the DEFO (shorts) weren’t particularly comfortable?

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________

2a. Did you wear the DEFO (shorts) for activities other than sport?

Yes ☐ No ☐

If you answered NO, can you please explain why you didn’t wear them outside of sport?

____________________________________________________________________________

____________________________________________________________________________

____________________________________________________________________________
2b. If you did wear them for other activities, how comfortable did you find wearing the DEFO (shorts)?

Please explain why you felt this, and list the activities that you wore them for
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

3. Were you pleased with the look of the DEFO (shorts)?

If you ticked box 1 or 2, please explain why you didn’t like the look of the shorts
_____________________________________________________________________________

4. Will you continue to wear the DEFO (shorts) for your sport?

Please explain why
_____________________________________________________________________________

5a. Do you feel that wearing the DEFO (shorts) has had ANY effect upon your sporting performance or physical activities that you have engaged in?

Yes ☐ No ☐
If you ticked yes, please list any positive and/or negative effects that you experienced

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Felt more confident wearing the shorts</td>
<td>Shorts felt</td>
</tr>
<tr>
<td>uncomfortable</td>
<td>1</td>
</tr>
</tbody>
</table>

5b. If you have listed any impacts upon performance, can you please rate how important you felt the impact of that impact was (1 = some impact, 3 = moderate impact; 5 = significant impact). Please add your score next to the impacts that you have listed above.

Example

<table>
<thead>
<tr>
<th>Pro</th>
<th>Con</th>
</tr>
</thead>
<tbody>
<tr>
<td>Felt more confident wearing the shorts</td>
<td>Shorts felt</td>
</tr>
<tr>
<td>uncomfortable</td>
<td>1</td>
</tr>
</tbody>
</table>

6. If you had the opportunity, would you change anything about the DEFO that you have trialled?

Yes ☐     No ☐

If you ticked yes, please briefly explain what you would change

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

Any other comments

______________________________________________________________________
______________________________________________________________________
______________________________________________________________________

Thank you for taking the time to complete this questionnaire
### Appendix 3. The QAREL Checklist

<table>
<thead>
<tr>
<th>Question (Q.)</th>
<th>Response</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the test evaluated in a sample of subjects who were representative of those to whom the authors intended the results to be applied?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Was the test performed by raters who were representative of those to whom the authors intended the results to be applied?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Were raters blinded to the findings of other raters during the study?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Were raters blinded to their own findings of the test under evaluation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Were raters blinded to the results of the accepted reference standard or disease status for the target disorder</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Were raters blinded to clinical information that was not intended to be provided as part of the testing procedure or study design?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Were raters blinded to additional cues that were not part of the test?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Was the order of the examination varied?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Was the stability (or theoretical stability) of</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
the variable being measured taken into account when determining the suitability of the time-interval between repeated measures?

10. Was the test applied correctly and interpreted appropriately?

11. Were appropriate statistical measures of agreement used?
## Appendix 4. The Pain Provocation Test Responses

<table>
<thead>
<tr>
<th>Test/Participant Number</th>
<th>ASLR</th>
<th>Faber’s Thrust Test</th>
<th>Thigh Thrust Test</th>
<th>Gaenslen’s Test</th>
<th>Squeeze Test</th>
<th>Number of Positive Tests</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>R=+</td>
<td>R=+</td>
<td>+</td>
<td>-</td>
<td>3</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>2</td>
<td>+</td>
<td>R=+</td>
<td>-</td>
<td>-</td>
<td>R=+</td>
<td>3</td>
<td>Intervention</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>3</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>4</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>5</td>
<td>Intervention</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>2</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>2</td>
<td>Intervention</td>
</tr>
<tr>
<td>7</td>
<td>-</td>
<td>R=+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td>Intervention</td>
</tr>
<tr>
<td>8</td>
<td>+</td>
<td>R=+</td>
<td>R=+</td>
<td>+</td>
<td>+</td>
<td>5</td>
<td>Intervention</td>
</tr>
<tr>
<td>9</td>
<td>-</td>
<td>L=+</td>
<td>L=+</td>
<td>+</td>
<td>-</td>
<td>3</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>10</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>4</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>11</td>
<td>+</td>
<td>+</td>
<td>R=+</td>
<td>R=+</td>
<td>+</td>
<td>5</td>
<td>Waiting-list control</td>
</tr>
<tr>
<td>12</td>
<td>+</td>
<td>R=+</td>
<td>L = +</td>
<td>L= +</td>
<td>+</td>
<td>5</td>
<td>Waiting-list control</td>
</tr>
</tbody>
</table>

261
-/+ indicates that the test provoked bilateral pain
R/L indicates that the test induced pain either on the right or left leg/side
ASLR refers to the active straight leg raise

<p>| | | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>-</td>
<td>R = +</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>2</td>
</tr>
<tr>
<td>14</td>
<td>L=+</td>
<td>L=+</td>
<td>-</td>
<td>L=+</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>R=+</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>+</td>
<td>+</td>
<td>+ = L</td>
<td>+</td>
<td>+</td>
<td>5</td>
</tr>
<tr>
<td>Totals</td>
<td>9</td>
<td>15</td>
<td>8</td>
<td>13</td>
<td>12</td>
<td>57</td>
</tr>
</tbody>
</table>
Appendix 5. Questionnaire Responses

The full questions and Likert-type scales are presented in appendix 2.

**Intervention Group Responses**

<table>
<thead>
<tr>
<th>Question / Response</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you wear the DEFO?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>How comfortable did you find the DEFO for sport?</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Did you wear the DEFO for other activities?</td>
<td>No need</td>
<td>No need</td>
<td>No need</td>
<td>Yes (for long distance driving). Comfort = 4</td>
<td>Yes (for work) Comfort = 3</td>
</tr>
<tr>
<td>Were you pleased with the look of the DEFO?</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Will you continue to wear the DEFO for your sport?</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4 (when I have pain)</td>
</tr>
<tr>
<td>Do you feel that the DEFO had any effects upon performance? If so what where the pros and cons?</td>
<td>Yes: Pros: Reduced pain which had inhibited performance Cons: N/A</td>
<td>Yes: Pros: Stability (3), reduced pain(5) and improved</td>
<td>Yes: Pros: Hip and hamstring support (4), more confident/less worried</td>
<td>Yes: Pros: Flexibility, power when running, sleep better after long distance</td>
<td>Yes: Pros: Eased pain (5), improved posture (5) Cons: Can be uncomfortable</td>
</tr>
</tbody>
</table>
### Cons?

<table>
<thead>
<tr>
<th>Cons:</th>
<th>power (5)</th>
<th>about injury (4)</th>
<th>driving because of less pain</th>
<th>able in groin region when worn &gt; 5 hours (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rolled down slightly at waist (1)</td>
<td>Cons: Shorts appeared to have stretched</td>
<td>Cons: N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Would you change anything about the shorts?

| No | No | Yes; they felt stretched. | Yes; waist was tight. Maybe use a drawstring | No |

### Any other comments:

“I have never experienced any benefit from straps, clothes, powders etc; absolutely nothing relating to sports products.

These shorts however are excellent and absolutely made a difference. I’ve heard they’re quite expensive though.”

“I look forward to trying them during games and seeing whether they will help improve performance through reduced pain and increased power.

Thanks for the opportunity.”

“I was happy to participate in this trial and am excited to see how they benefit my football season. I believe it is a great product and hope it is very successful.”

“Very happy with the shorts.”
### Question / Response

<table>
<thead>
<tr>
<th>Question / Response</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you wear the DEFO?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>How comfortable did you find the DEFO for sport?</td>
<td>5</td>
<td>5</td>
<td>1</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Did you wear the DEFO for other activities?</td>
<td>No as they were soggy after sport</td>
<td>Yes</td>
<td>Yes</td>
<td>No need (found them tight for sitting)</td>
<td>No need</td>
</tr>
<tr>
<td>How comfortable did you find the DEFO for other activities?</td>
<td>Comfort = 5</td>
<td>Comfort = 5</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Were you pleased with the look of the DEFO?</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Will you continue to wear the DEFO for your sport?</td>
<td>5</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Do you feel that the DEFO had any effects upon performance?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Identify the pros and cons, and rate the impact upon performance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Pros: More stable when running (1)</td>
<td>Pros: Feeling of tightness</td>
<td>Pros: Felt much more stable in the pelvis (3), made me more aware of my posture (3)</td>
<td>Pros: Felt I had a greater range of movement when doing certain activities such as lunging and squats (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cons: Possible decrease in vital capacity, felt increase in blood</td>
<td>Cons: Starting to wear</td>
<td>Cons: Too tight to sit comfortably (3)</td>
<td>Cons: Too tight to sit comfortably (3)</td>
<td>Cons: Too tight to sit comfortably (3)</td>
<td>Cons: Too tight to sit comfortably (3)</td>
</tr>
<tr>
<td><strong>pressure when donning</strong></td>
<td><strong>from an acute adductor strain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cons:</strong> tight around waist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Would you change anything about the shorts?** | **Yes. Integrate a loose pair of shorts into the DEFO** | **Yes. Shorter leg (I ordered them too long)** | **Yes. Less seams between the legs and no silicon on waist band** | **Yes. Make loose at the waist. Maybe include a zip** | **No** |

Any other comments:

“I think there is huge scope with these orthoses for tailoring the reinforcements to individual requirements i.e I have a posteriorly rotated sacrum that is contributing to my SIJ pain. Extra reinforcements on one side may help alignment?!”

“I am so grateful to have the DEFOs they have made such a difference and resolved my pelvic and hamstring pain. Thank you.”
10 References


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