Ankle Sprain Prevention – The Effect of the Nike Free Shoe in Elite Male Soccer Players

by

NADINE ALETHIA NEMBHARD

B.Sc.P.T., The University of British Columbia, 1999

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ABSTRACT

The original purpose of this investigation was to determine if soccer players who performed an agility training program in a specialized training shoe would have a lower incidence of acute ankle sprains as compared to controls. Two elite male college soccer teams participated in the study. The experimental team performed an agility training program two to three days per week over a three month period wearing the Nike Free Trainer. Data on ankle sprain incidence throughout the season was collected, as well as scores on tests of ankle strength, static balance, dynamic balance, agility and self-reports of ankle function. These scores were compared to those of the control team. Statistical analysis showed a statistically significant improvement in the experimental team members in the anteromedial reach direction of the dynamic balance test ($p=0.001$). This group also showed positive trends in ankle strength ratio and five of the eight other reach directions of the dynamic balance test. Unfortunately, pre-test, post-test statistical analysis was possible for only half of the experimental team subjects. Post-test data was not generated for the other half of these subjects due to unrelated injury or subject noncompliance. Lack of pre-test data due to subject non-compliance in the control team hindered between group statistical comparisons. This study uncovered promising trends as to the potential for gains in dynamic balance as a result of agility training with Nike Free Trainer. This study also established the reliability of three clinical tests of ankle strength, static balance and dynamic balance. Future well-designed studies are recommended to research this area further to discern the effect of this agility training program on dynamic balance and establish its' effect on ankle sprain incidence.

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CHAPTER 1. INTRODUCTION

With our ever-increasing knowledge of injury mechanisms and pathophysiology, there is an impetus to not only treat injuries that have occurred, but also to prevent injuries from occurring. In an athletic population, injury prevention is of particular importance, as the time lost as a result of injury can be very costly on a number of levels and to a number of people.

Ankle sprains are the most common injury amongst soccer players, and as such, numerous studies have been conducted in the area of ankle sprain prevention. Various preventative measures and programs exist, each with unique advantages and disadvantages. Contemporary theory suggests that impairments in balance and proprioception are the primary cause of ankle sprains. Previous studies have successfully highlighted the connection between improvements in balance and proprioception and reductions in ankle sprain incidence. These studies have primarily utilized static methods of retraining (e.g. balancing on a wobble board). In order to maximize the specificity of the training stimulus, a dynamic balance training program, involving the movement patterns used during soccer would be ideal. As such, this study investigates the use of a soccer-specific agility training performed with a specialized shoe, the Nike Free, which was designed to improve ankle strength and balance.

1.1 Purpose of the Investigation

The primary purpose of this study was to investigate whether an agility training program performed with the Nike Free shoe would affect the incidence and severity of ankle sprains sustained by elite male soccer players over the course of one competitive season. The secondary purpose of this study was to determine whether agility training in the Nike Free shoe would affect other markers of ankle function. The markers of interest were ankle strength, static balance, dynamic balance, agility, and scores on a subjective outcome measure of ankle function. The tertiary purpose of this study was to determine whether trends in the aforementioned variables were different in subjects with a history of ankle sprains as compared to those with no ankle sprain history. The final purpose was to determine the reliability of the outcome measures selected to evaluate ankle strength, static balance and dynamic balance.

1.2 Significance of the Investigation

Agility training programs have been shown to be an effective means of injury prevention in athletic populations. Studies involving such programs have historically had subjects perform their agility-training program in standard athletic shoes. Agility training with the Nike Free stands to offer the athlete a means by which to address some of the key components of ankle sprain rehabilitation and prevention in sport-specific patterns. Recent studies on agility training with the Nike Free shoe have reported its' effectiveness in improving facets of ankle function, as well as preventing injury.

The body of research on the Nike Free shoe is limited at present; however, it stands to reason that combining the Nike Free shoe with agility training could magnify their individual effects, particularly in an arena where optimal foot and ankle function is key. This is an area that has not yet been researched.

1.3 Statement of the Problem

Ankle sprains are the most common athletic injury and are the most prevalent injury amongst soccer players[1,2]. Time lost due to the sequela of pain and decreased function following an ankle sprain can be very costly to the success of the individual athlete, as well as to the success of his or her team. It has been estimated that 55% of those who sustain an ankle sprain do not seek medical treatment for rehabilitation of their injury [5]. As a result, many athletes fail to restore the components of optimal ankle function that are the cornerstones of ankle sprain rehabilitation, making them more likely to suffer with persistent symptoms, compete at a suboptimal level, sustain another ankle injury or develop chronic ankle instability. A simple way of integrating ankle sprain rehabilitation principles into training sessions could help to ameliorate this unfavorable sequela.

Ankle taping and bracing are the two most widely used methods of ankle sprain prevention in an athletic population; however, researchers now believe that the prophylactic effect of taping and bracing may be attributable to enhanced proprioception rather than to true mechanical stabilization [4,6,7]. As such, current theory suggests that ankle sprain prophylaxis should focus on improving the functional stability of the ankle complex by optimizing foot and ankle strength, balance and proprioception. Accordingly, numerous recent studies have investigated the effect of agility and balance training programs on ankle sprain prevention and have reported a reduction in injury rates in those who participate in such programs [18,64,65,68].

The Nike Free shoe was designed to mimic the challenges placed on the foot during barefoot running. Barefoot training has been advocated as a means to improve proprioception, impact attenuation and foot and ankle musculature activation [13,32]. Recent studies have reported improvements in various markers of ankle function in healthy subjects that engaged in agility training with the Nike Free shoe [8]. Combining the noted positive effects of agility training programs in general with the positive effects of agility training in the Nike Free shoe could prove to have a protective effect on the ankle by enabling the athlete to address some of the key components of ankle sprain rehabilitation and prevention while utilizing movement patterns and skills that are specific to their sport.

1.4 Limitations and Delimitations

(1) Study Design-

The original study design involved three teams of male soccer players. The Experimental Team A was to perform the agility training program in the Nike Free Trainers, the Experimental Team B was to perform the same agility training program in their regular cross training shoes and the Control Team was to have no change to their footwear or regular training regime. The two Experimental Teams were to perform their agility training program three times per week in the three-month pre-season period, then continue the program two times per week during their competition season. All subjects from all teams were to go through the same series of tests at the beginning of the pre-season period (week 0), at the beginning of the competition season, (week 12), and then again at the end of the competition season (week 22).

Due to continual compliance issues with the participant teams, the study design was subject to numerous alterations. Eventually, these repeated alterations resulted in significant changes in the study design, which significantly compromised the value of the data generated by the study. Because of ongoing difficulties scheduling the subjects for their pre-season assessment within the time frame dictated by the study, Experimental Team A began their agility training program ten weeks later than desired. As a result, this team participated in only two, rather than the desired three, testing sessions.

Due to ongoing difficulties in scheduling the Control Team for their pre-season assessment, they missed their window of opportunity and only a post-season assessment could be done with them. Because of their ongoing inability to comply with the requirements of the study the Experimental B Team resigned from the study.

The remainder of this document describes the study as it was eventually implemented rather than how it was originally planned as described above.

(2) Testing-

I) Any subject who sprained their ankle, or sustained any other injury that may have affected their balance or ability to complete testing or training protocols was excluded from completing the remainder of the study. The data lost from the subjects that had to withdraw from the study because of injury may have affected the outcome of data analyses.

II) The single-limb balance test used in this study has not been previously formally validated. A pilot study was conducted to gauge the reliability of this testing protocol. Single-limb balance tests have been used in various previous ankle sprain prevention studies; however, this particular protocol was chosen for use in this study to ensure that it would be challenging enough to highlight impairments in subjects of this caliber.

(3) Subject-

I) While the Experimental Team subjects were asked to refrain from wearing ankle taping or bracing during their agility training program, they were not prohibited from doing so during their training sessions and games. They were asked to record their use of any type of external stabilizer. The use of external stabilizers may have reduced the ankle sprain risk of selected subjects as compared to those who did not use stabilizers.

II) Differences in an individual player's baseline level of ankle function, general strength and flexibility, style of play and fitness level may have affected their ankle sprain risk. Subjects who normally wear orthotics or very supportive shoes may have responded differently to the Nike Free shoes as compared to those who do not A subject's injury history may have an effect on their potential to improve their balance and agility, or on their risk of exposure to injury. Also, a subject's participation in other, particularly high-risk, sports or recreation activities may have increased their risk of exposure to ankle sprains.

(4) Team-

I) Differences in coaching style and philosophy may influence the intensity and aggression of a team, thereby influencing the team members' risk of exposure to ankle injury. In addition, some coaches may or may not utilize drills or techniques that facilitate improved strength and balance, which may have influenced the team members' ankle function and/or risk of exposure to ankle injury.

II) Three elite male soccer teams were selected for the study. The teams' training and competition schedule were quite similar, as was their exposure to playing in poor weather conditions.

III) Teams averaged comparable scores on the Ankle Injury Questionnaire, indicating a fairly equal distribution between the teams with respect to the number of players with an ankle sprain history.

1.5 Hypotheses

It was hypothesized that:

1. Agility training with the Nike Free shoe will result in a decrease in the incidence of acute ankle sprains.
2. Agility training with the Nike Free shoe will result in a decrease in the severity of acute ankle sprains.
3. Agility training with the Nike Free shoe will result in an increase in ankle inversion and eversion strength.
4. Agility training with the Nike Free shoe will result in an increase in static and dynamic balance.
5. Agility training with the Nike Free shoe will result in an increase in agility.

CHAPTER 2. LITERATURE REVIEW

2.1 Ankle Sprains

Ankle sprains are reported to be the most common injury amongst recreational and competitive athletes, particularly amongst athletes in contact sports like soccer and basketball [4,18,22]. The recurrence rate is high, especially for athletes sustaining lateral ankle sprains, where it has been suggested to be as high as 70 to 80% [19,22]. Not all ankle sprains are simple; as many as 20 to 50% of those injured may develop residual symptoms and instability which may last 6 weeks to 18 months post-injury [6,22,23,28]. According to a study by Anandacoomarasamy, a surprising 74% of athletes referred to a sports medicine clinic post-lateral ankle sprain had ongoing symptoms of pain, weakness, swelling and/or instability persisting 1.5 to 4 years after their injury [21]. As these athletes return to activity with suboptimal ankle function, they are often reduced to playing at a suboptimal level and are at greater risk of sustaining another ankle sprain or developing chronic ankle instability.

2.1.1 Anatomy

The ankle complex consists of the talocrural, subtalar and interior tibiofibular joints. The congruity of the joint surfaces, the static defense supplied by the ankle ligaments, and the dynamic defense supplied by local contractile structures, all contribute to stability of the ankle joint complex [19]. One of the contributors to bony stability is the wedge-shaped articular surface of the talus within the talocrural joint. This wedge is wider anteriorly than posteriorly, resulting in greater articular stability of the talocrural joint in a position of ankle dorsiflexion. In a position of ankle plantarflexion, the articular stability is reduced, thus, the ligamentous and contractile elements must play a greater role in maintaining stability of the ankle complex.

Ligamentous support of the talocrural joint is provided by the lateral collateral (anterior talofibular, calcaneofibular and posterior talofibular ligaments) and medial collateral ligament complexes (Figure 1). The subtalar and inferior tibiofibular joints also have their network of ligamentous structures to support them. Dynamic support of the ankle complex comes from the numerous musculotendinous structures that cross and support the ankle joints. The ankle invertors and evertors are believed to have a particularly important role to play in stabilizing the ankle complex in the prevention of ankle sprains. In providing dynamic stability to the ankle joint complex, the eccentric function of these musculotendinous structures is of particular importance [19].

Figure 1. Ligaments of the Ankle Joint

The ankle joint complex includes the talocrural, subtalar and inferior tibiofibular joints, each of which is supported by a network of ligaments.

Figure 1 has been removed because of copyright restrictions. The image showed the bony and ligamentous anatomy of the ankle complex and was obtained from the Hughston Health Alert website © 2007 (http://www.hughston.com/hha/b_16_4_3a.jpg).

2.1.2 Mechanism of Injury

Ankle ligament injuries occur as a result of excessive motion in a given direction that exceeds the restraining capacity of the static and dynamic stabilizers of the ankle. Lateral ankle sprains are by far the most common type of ankle sprain; the literature suggests that in an athletic population, the lateral ligament complex is involved in 85 to 90% of all ankle sprains [24]. Lateral ankle sprains usually result from excessive plantarflexion and inversion of the ankle, and most commonly affect the anterior talofibular ligament [18,19]. Subtalar ligament injury usually occurs with a lateral ankle sprain mechanism; one study reported that

80% of subjects with an acute lateral ankle sprain had concurrent subtalar ligament involvement [19,20,22]. Medial collateral ligament injuries are rare, suggested to account for only 5% of all sprains [18.] This is due to the considerable strength of the medial collateral ligaments and the decreased likelihood of an eversion mechanism of injury as compared to an inversion mechanism. These eversion injuries typically produce more severe disability in the form of persisting pain and chronic instability [6]. Inferior tibiofibular joint sprains account for 10% of all sprains and are usually due to a hypereversion mechanism, but can also result from hyperinversion [19,23]. Inferior tibiofibular joint sprains are also associated with a higher level of disability and slower recovery time.

Traditionally, ankle sprains have been attributed to a sudden, dramatic force that overcomes the passive, mechanical stability of the ankle. While this is often the mechanism of injury in traumatic and contact injuries, many authors now subscribe to the proprioceptive theory of ankle sprain mechanism. This theory suggests that most ankle sprains occur due to improper foot position at or just before foot strike [13,30,31,32]. This occurs due to a misconception of the actual amount of ankle inversion present at or before foot strike. As a result, the athlete does not make the appropriate adjustments to compensate for the degree of ankle inversion, either by failing to reposition the limb prior to foot strike, and/or by failing to recruit the appropriate musculature to support the ankle on foot strike. This is seen especially during athletic activity, where the fast pace means that there is insufficient time to correct for a suboptimal loading position. This proprioceptive theory places deficits in joint position sense as the primary cause of ankle sprains and appears to offer an appropriate explanation for the mechanism behind non-contact inversion ankle sprains.

2.1.3 Chronic Ankle Instability

An ankle sprain is often perceived as a relatively simple injury and individuals often quickly return to normal occupational and athletic activities. While the initial symptoms may resolve quickly, the recurrence rate post-ankle sprain is high, particularly in individuals sustaining a lateral ankle sprain. It has been suggested that as many as 20 to 50% of those who sprain their ankle will experience some form of chronic pain or instability [6,28]. This has led researchers to question the pathology underlying this trend of repeated ankle sprains.

A lateral ankle sprain not only damages the ligamentous structures of the ankle complex, but also affects the local musculotendinous and neuromeningeal structures, which can result in neuromuscular impairments. These neuromuscular impairments may present as decreased balance, muscle strength, range of motion, joint position sense or cutaneous sensation, or may present as impaired nerve conduction velocity or peroneal muscle firing [19.20,22,29,30].

These ligamentous and neuromuscular deficits, in isolation or collectively, can produce chronic ankle instability (CAI). Hertel defined CAI as 'repetitive bouts of lateral ankle instability, resulting in numerous ankle sprains' [22]. CAI may be the result of mechanical instability or functional instability, or a combination of the two [3,22]. Mechanical instability (MI) refers to an increase in the accessory movements at a joint, most often due to damage of local ligamentous or osseous structures [19,20,22,23]. Functional instability (FI) is defined as 'the occurrence of repetitive ankle instability and the sensation of joint instability due to the contributions of proprioceptive and neuromuscular deficits' [3,17,21,33,34].

In those with CAI, the level of pain and disability increases with each successive sprain; therefore, it is suggested that the goal of acute ankle sprain treatment should be to prevent the development of CAI[18]. CAI can result in suboptimal athletic performance or may prohibit an athlete from returning to their sport altogether. While little can be done to re-establish the lacking passive stability of MI, rehabilitative and preventative strategies can have an effect on the neuromuscular deficits of FI. As such, numerous authors strongly recommend that interventions aimed at correcting these neuromuscular deficits be the focus of rehabilitative and preventative programs [19,20,22,26,30,33,34,35,36,37].

2.2 Ankle Sprain Predictive Factors

2.2.1 Acute Ankle Sprain

Research into factors predictive of an acute ankle sprain have produced few solid answers. Factors such as abnormal postural stability and muscle strength have been cited as risk factors in acute ankle sprain incidence [26,40]. Surprisingly, according to the literature, generalized joint laxity and foot shape (e.g. pronated, supinated) appear not to be predictive factors; however clinically, these two factors appear to pose relevant risks [26,40]. Willems et al identified numerous intrinsic risk factors, including dorsiflexion range of motion and strength, coordination and muscle reaction time; however, other studies have contradicted these findings [38]. This contradiction in findings between studies of predictive factors prompted Beynnon, in his 2002 literature review, to report a lack of consensus as to whether height, weight, limb dominance, muscle strength, muscle reaction time and postural sway are predictors of acute ankle sprains [26].

2.2.2 Recurrent Ankle Sprains

The factor most predictive of suffering a lateral ankle sprain is a history of at least one previous ankle sprain [2,20,21,24,25]. Beyond this, factors related to recurrent ankle sprains and the development of CAI have not been clearly established in the literature, largely due to variations in the way in which authors have defined their subjects, as well as in the methods selected to assess these subjects. Thus, while some authors have reported impaired static balance in those with CAI and FI [40,41], others report that the relationship is indeterminate [42]. Pintsaar has reported differences in postural control strategies, characterized by an increased use of hip versus ankle strategy in those with FI [32], while other authors have reported impaired dynamic balance in those with CAI/FI [41,42]. Alterations in invertor and evertor muscle function have been reported by numerous authors [17,39,44,45]; however, this has been countered by other studies, resulting in uncertainty as to the importance of muscle strength as a predictive factor, especially in comparison to other neuromuscular control factors, like joint position sense and balance [46].

2.3 Ankle Injuries in Soccer

2.3.1 Incidence

Studies have reported the incidence of foot and ankle injuries in soccer players to be between 3 and 9 injuries per 1000 playing hours [23]. Ekstrand's study of 639 soccer players found that ankle sprains accounted for 17 to 21% of all soccer injuries incurred over a year [2]. Others have estimated the ankle sprain incidence in soccer to be as high as 31% [7].

2.3.2 Mechanism of Injury

In the world of soccer, an athlete has a 4 to 6 times higher chance of sustaining an injury during a game as compared to a training session [38]. Giza et al reported that foot and ankle injuries were more likely to occur during foul play, from direct contact by a medially or laterally directed force, in a weight bearing position [23]. In addition, Ekstrand has reported that a soccer player's dominant leg is more likely to incur an ankle sprain than the non-dominant leg [1]. As the focus of activity during a soccer is on the ball, it is understandable that the ankle, with its' close proximity to the ball, is such a prime target for injury.

2.3.3 Factors in Ankle Sprain Incidence in Soccer

About 20 to 25% of soccer injuries are reported to be repeat injuries of the same location and type [38]. In a study by Ekstrand, of the 36 sprained ankles incurred over a year, 47% of them had been sprained previously[1]. According to Tropp et al, over the course of a soccer season, athletes have a 25% chance of spraining their ankle if they have sprained it previously; in the absence of a history of ankle sprain, this chance of spraining decreases to 11% [3]. These findings have lead researchers to stress the importance of proper diagnosis and management of first-time injuries to reduce the chance of recurrent injuries.

As previously mentioned, medial collateral and inferior tibiofibular ligament sprains are relatively rare. Reports have suggested that 85 to 90% of ankle sprains involve the lateral collateral ligament complex in a general athletic population, with only a small percentage of medial ankle sprains. Some authors have suggested that in the soccer population, there may be a higher than normal incidence of medial ankle sprains [23]. This increased incidence may be due to the fact that, as compared to a general athletic population, a soccer players' ankle is exposed to extremes of all ankle ranges of motion and their medial foot is used to a high degree for ball handling activities.

Other factors have been investigated as potential risk factors for ankle sprains in soccer players. Kofotolis' 2007 study of 312 male amateur soccer players reported that soccer-related ankle sprains were primarily contact in nature, were most likely to occur during the first 2 months of the season, and were more likely to occur toward the end of a game [47]. Reports on the effect of player position have been inconsistent [1,47]. Type of playing surface (natural grass versus artificial turf) has been shown not to have an effect on acute ankle sprain incidence [48,49]. Elite and professional soccer players have been shown to have a higher sprain incidence versus more recreational players [54].

2.4 Ankle Sprain Prevention

2.4.1 External Ankle Supports

Ankle bracing and taping are the two most commonly used types of external ankle supports, and are also the most frequently researched methods of ankle sprain prevention. A recent Cochrane review, based on the data from fourteen randomized clinical trials, concluded that external ankle supports can prevent ankle sprains during high-risk sports such as soccer, especially in athletes with previous ankle sprains [53]. They have been shown to limit inversion range of motion, improve the strength of the muscular response to perturbation, decrease the velocity of inversion, and decrease postural sway in those with FI [54].

Numerous studies have evaluated the efficacy of ankle taping in preventing ankle sprains, particularly in those with an ankle sprain history [3,4,55,56,57,58]. Ankle taping is proposed to provide external stability to the ankle ligaments without hampering the normal mechanics of the joint complex [55]. Taping has been shown to reduce ankle sprain incidence, again, particularly in those with a history of previous sprains [4,57,58]. Many comparative studies have reported a lower ankle sprain incidence in braced as compared to taped ankles, leading several authors to advocate bracing as the preferable mode of external ankle support [11,57,58,59].

Despite the favorable reports on external ankle supports in the literature, limitations of these methods do exist. Numerous authors have commented on the limited holding capacity of taping, reporting that taping loses as much as 40% of its range of motion restriction capacity after ten minutes of exercise and that after one hour of exercise, taping no longer provides significant restriction to ankle movement [7,9,12,15,57]. Studies on the holding capacity of ankle braces have also noted loosening with activity [55]. Bracing may not be effective for people that have sustained more than five sprains on the same ankle [56]. In addition, it has been suggested that ankle supports, by increasing rigidity of the foot and ankle complex, may increase the risk of injury to the hip and knee [54]. Although it has been suggested that external supports negatively effect athletic performance, the majority of studies have reported the contrary [4,12,14,15,54,61].

Some intercollegiate and professional teams mandate that all of their athletes prophylactically tape their ankles for all practices and games. Clinical reason would suggest that such long-term taping of a healthy ankle may result in these athletes becoming ‘tape dependant’ and may negatively affect their natural level of ankle function. Data on the resultant ankle function without tape (e.g. joint position sense, ankle strength and dynamic balance), as well as the incidence of injury to other lower extremity joints following long-term prophylactic taping would be interesting; however, this data does not exist at present.

Research suggests that the mechanical effect of external ankle support is limited to restricting the extremes of ankle motion [52]. While the force needed to sprain an ankle is not known, it is doubtful that taping or bracing alone could withstand this force, especially as activity progresses and their mechanical effect lessens [6,7,9,11]. As such, it is now believed that the primary protective effect of bracing and taping is via enhanced proprioception [6,11,13,56]. Traction or pressure on the skin from the external support provides cutaneous cues as to foot and ankle position and orientation. These cues are used in the anticipation of foot contact to properly position the foot and ensure appropriate muscle recruitment, thereby minimizing excessive loading through the ligamentous structures upon contact [6]. This theory is supported by Robbins et al, who found that foot position error was 49.4% better in those with taped versus untaped ankles [13].

Soccer players are much more likely to tape rather than brace their ankle for training sessions/games. This is most often due to complaints of braces fitting poorly into the soccer boot and limiting ankle range of motion, thus hampering athletic performance. In addition, wearing both shin guards and an ankle brace is often seen as bulky and uncomfortable. Considering the limitations of ankle taping in terms of cost effectiveness[16] and duration of support, and the limitations of bracing in terms of fit and function, an alternative mode of ankle sprain prevention for soccer players would be desirable.

2.4.2 Balance Training

Ankle injury can result in impaired static and dynamic balance; if these deficits are not addressed prior to return to activity, there may be a higher likelihood of re-injury [55]. Proprioception, or joint position sense, is a key factor in one's ability to attain and maintain balance. According to Emery: "the ability to maintain balance is based on the complex interaction between the somatosensory, vestibular and visual functions and coordination of movements with muscle activity" [87]. The notions that proprioceptive faults may be at the root of ankle sprains, and that external ankle supports may have a primary proprioceptive function, have led support to the concept of targeting proprioception, via activities like balance training, to reduce ankle sprain incidence [11,60].

Wester et al, in a study on subjects with primary ankle sprains, reported a reduction in the number of recurrent ankle sprains and in the number of subjects with FI after a 12-week wobble board balance training program [64]. Verhagen et al also reported a reduction in lateral ankle sprain incidence in those with a history of ankle sprains that engaged in balance board training over the course of a season [18]. Balance training has been shown to improve postural sway and ankle joint position sense, and facilitate the control of inversion, all factors felt to reduce ankle sprain incidence [36,39,53,54,65]. In addition, Pintsaar et al reported that the over-utilization of the hip strategy to maintain balance seen in those with FI was normalized following a balance training program [32].

2.4.3 Ankle Strength

Although ankle strengthening exercises are routinely prescribed as a part of ankle sprain rehabilitation, and impaired muscle function has been suggested as a factor in ankle sprain risk, there is a lack of studies that directly investigate the relationship between ankle strength and ankle sprain prophylaxis. Tropp & Odenrick suggested that the ankle weakness noted in those with CAI may be due to inadequate rehabilitation and secondary muscular atrophy [66]. Optimizing ankle muscle function would seem a viable mode of preventing sprains, especially as it has been suggested that in the face of an inversion ankle sprain, the peroneal musculature can develop a protective eversion moment that is five times greater than what could be provided by taping or bracing [45]. Docherty et al found that individuals with FI who participated in an ankle strengthening program improved their joint position sense, in addition to improving their strength [67]. Considering the proposed link between lacking joint position sense and ankle sprain incidence, it is plausible that improving ankle strength may help to prevent ankle sprains. DeMaio seems to support this postulate, stating that restoring strength may be amongst the most important factors in preventing repeat injury and chronic instability [25].

2.4.4 Agility Training

Agility training programs are usually characterized in the literature as programs that emphasize dynamic balance, agility, and sport specific exercises. The goal of these training programs is to enhance anticipatory control of joint position.

Eils & Rosenbaum reported improved joint position sense, postural sway and muscle reaction time in patients with FI after participating in a training program once per week for six weeks [65]. These subjects also had a decreased incidence of recurrent sprains and a reduced sense of instability at one-year follow-up. Wedderkopp also demonstrated a reduction in ankle sprain incidence following participation in a program designed to improve functional strength and proprioception [68]. A similar protective effect has been reported with proprioceptive/agility training and knee ligament injuries [69]. Myer has also shown that such programs can reduce aberrant torque production during functional activities, resulting in improved biomechanics [70].

Agility training and testing has often been a key component of these functional training programs. Agility remains a difficult entity to describe, and according to Sheppard and Young, within the sports science community no precise definition has been agreed upon [88]. They go on to propose a definition of agility as: a rapid whole-body movement with change of velocity or direction in response to a stimulus''. This definition highlights both the physical (strength, power, change of direction speed) and cognitive (anticipation, visual scanning, pattern recognition) components of agility, and supports the authors assertion that new tests of agility are needed that assess both the physical and cognitive components.

2.4.5 Shoes

A study by Waddington and Adams suggests that the smooth insoles commonly used in soccer boots may limit the ability of the sole of the foot to convey information about foot position, which may increase the risk of ankle sprains [64]. Their study found that movement discrimination was significantly worse in soccer boots with smooth insoles as opposed to barefoot, and that textured insoles placed in the soccer boots significantly improved movement discrimination. Robbins et al found that athletic footwear significantly reduced foot position sense and stated that improving footwear may reduce the incidence of ankle sprains [13]. Robbins and Waked reinforced the idea that efforts need to be made to increase the awareness of foot position while in shoes, possibly through the use of insoles that produce plantar deformation [6]. Barrett and Bilisko's review of the role of shoes in ankle sprain prevention proposed that the ideal shoe should allow for normal subtalar joint motion, and provide adequate proprioceptive input and traction [27].

2.5 Barefoot Training

Researchers and athletic coaches have long been interested in the differences between shod and barefoot populations in terms of injury incidence and athletic performance. It is now felt that some of these differences may have a significant effect on ankle function and ankle sprain incidence.

Authors suggest that our innately accurate sense of foot position becomes distorted and inaccurate when placed in highly shock-absorbing modern footwear [6,27,32]. Robbins found that athletic footwear increased foot position error by 107.5% as compared to barefoot conditions [13]. Secondly, barefoot activity is reported to facilitate adaptations that allow impact absorption and protect against overload injuries [32]. The sensitive plantar surface of the foot transmits pain and pressure impulses indicative of overload or injury. In response to such stimuli, the individual should respond by altering their mechanics to better absorb shock and reduce stress through the plantar foot [74]. Modern footwear, with its thick and cushioned sole, diminishes this source of information; therefore, a shod individual is less inclined to employ adequate impact-reduction strategies that would minimize tissue overload [32,74]. Finally, in the absence of this bulky footwear, the ankle and foot muscles have greater demands placed upon them, which facilitates gains in muscle recruitment, strength and endurance [32].

As mentioned previously, current theory suggests that poor proprioception, resulting in inadequate anticipatory recruitment of foot and ankle muscles, is a key factor in inversion sprains [6,24]. Preventative strategies aimed at improving foot position awareness and facilitating intrinsic foot muscle recruitment could arguably play a role in reducing ankle sprain incidence. Particularly for soccer players, who essentially use their feet as we would our hands, optimal proprioception and muscle recruitment is crucial. The answer may be either through increased barefoot activity, or through the employment of footwear modifications that facilitate plantar tactile input, thereby enhancing foot position sense and foot intrinsic activity [6,32].

2.6 The Nike Free Shoe

The Nike Free shoe was designed to mimic the challenges placed on the foot during barefoot running. The shoe design was modeled upon analysis of the mechanics of barefoot running based on force plate, electromyographical and motion capture data. The shoe has a highly flexible, deeply grooved outsole, a low heel height, a widened toe box area and a very thin and soft upper (Figure 2). These modifications are proposed to facilitate natural gripping and increased flexibility within the shoe, as well as a to produce a more uniform pressure distribution throughout the foot during loading. The Nike Free Trainer 5.0, the specific model used in this study, also has forefoot strapping, designed to stabilize the foot during speed and agility activities.

Figure 2. The Nike Free

A highly flexible outsole, low heel height and widened toe box are amongst the modifications designed to make the Nike Free mimic barefoot conditions.

Figure 2 has been removed due to copyright restrictions. The images showed the Nike Free shoe, obtained from the Sneaker Park website (www.sneakerpark.com), the Lechlaufer website (www.lechlaeufer.de) and the Yam website (www.hercafe.yam.com).

Two studies have demonstrated the potential of the Nike Free aiding in ankle sprain prophylaxis. One study followed fifty subjects who wore the Nike Free shoe during their warm-up for thirty minutes, three to four times per week, over a five-month period [8]. As compared to the control subjects, who did the same warm-up in a regular training shoe, the Nike Free shoe group showed increased strength of the toe flexors and ankle plantarflexor and invertor muscles, increased cross sectional area of the foot intrinsics, and improved balance/neuromuscular performance. They also sustained 20% fewer lower limb injuries/pain episodes over the subsequent twelve months as compared to the control group. A subsequent study (Bruggemann et al 2007, unpublished) examined the effects of a three-week agility and balance training program in the Nike Free shoes. They reported significant improvements in markers of neuromuscular performance, most notably muscle strength, agility and balance.

CHAPTER 3. METHODOLOGY

3.1 Participants

Three elite male college soccer teams were recruited to participate in the study. The percentage of players on each team with a history of ankle sprains, as well as subjects' scores on a Functional Instability Index (Appendix A) were compared to ensure that the teams were evenly matched.

Excluded from the study were those subjects determined to have gross mechanical and/or functional ankle instability on clinical assessment by the study physiotherapist. Also excluded were those unwilling or unable to participate in all aspects of the study, including those with significant recent or ongoing injuries or pathologies and/or medical conditions that impaired their balance or ability to perform the testing and/or training components of the study.

3.2 Testing

A series of tests was used to assess each subject's ankle function:

Ankle invertor and evertor strength: These were measured manually using the Lafayette Handheld Dynamometer (Lafayette Instrument Company). Subjects were positioned in a long sitting position. A strap was used to secure their test-leg to the table to stabilize the lower leg and help isolate the test movements to the ankle. Each subject performed three five second trials of maximal isometric inversion and eversion on each leg, using a 'make' test protocol as per Burns [75]. The peak force for each trial was recorded. The average of three trials was calculated for use in statistical analysis. These mean scores were also used in calculating the inversion:eversion strength ratio for each subject. The same physiotherapist performed all ankle strength measurements throughout the study.

Test-retest reliability was established prior to commencement of the study, using the same protocol with a small group of healthy volunteers (Table 2). These volunteers performed two trials of each movement, on two occasions according to the protocol listed above. The scores for the two trials on occasion one were averaged, as were the scores for the two trials on occasion two, and then these averaged scores were used in statistical analysis.

Static balance: This was measured via a single limb standing test. The barefoot subject stood on a foam surface and was instructed to maintain this position for thirty seconds with their contralateral hip and knee flexed to ninety degrees and their arms across their chest. The test was repeated twice per leg with the eyes open, and then twice again per leg with the eyes closed. The number of times that the subject lost their start position (e.g. the contralateral leg lowered to the floor, their arms became uncrossed or their body lost vertical orientation) was determined on video review, tallied and recorded for each trial. The same physiotherapist judged all static balance tests throughout the study.

Similar static balance tests on a foam surface have been reported in the literature [76,77,78]; however, none of them utilized the same combination of balance challenges and definition of a balance infraction as was used in this study. Test-retest reliability was established prior to commencement of the study, using the same protocol with a small group of healthy volunteers (Table 3). Subjects performed two trials each of eyes open balance and eyes closed balance, on two occasions, as per the protocol described above. The scores generated on trial one and two of the first occasion were averaged, as were the scores generated on trial one and two of the second occasion. These averaged scores were then used in statistical analysis.

Dynamic balance: This was measured via the Star Excursion Balance Test

(SEBT) (Figure 3). While maintaining balance in single limb stance, the barefoot subject reached the contralateral leg as far as possible along each of the eight lines of a star-shaped grid, lightly touching the line at the furthest point possible. The distance from the center of the grid to this point was measured with a measuring tape. Subjects were given two trials of each reach direction per leg. Their maximum reach distance was measured for each trial, the scores were averaged and then converted to represent reach distance as a percentage of the subject's leg length. This was done for each reach direction on both legs.

The SEBT has been shown to be valid and reliable as a research and clinical assessment tool [80,81], and has been deemed sensitive enough to distinguish between those with versus without chronic ankle instability [43,79]. Test-retest reliability was established prior to commencement of the study, using the same protocol with a small group of healthy volunteers (Table 4). The volunteers performed two trials of each direction, on each leg, on two occasions. The scores for the two trials on occasion one were averaged, as were the scores for the two trials on occasion two. These average scores were then used in statistical analysis.

Figure 3. The Star Excursion Balance Test

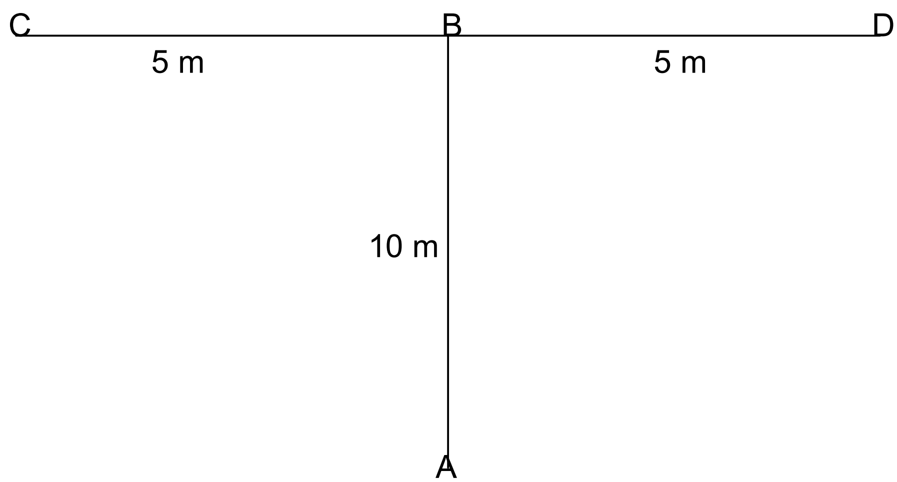
Reach directions for the SEBT in right and left single limb stance. There is a 45 degree angle between each line and those adjacent to it.

Figure 3 has been removed due to copyright restrictions. The image diagrammed the layout of the Star Excursion Balance Test and was obtained from Olmsted LC et al. Efficacy of the Star Excursion Balance Tests in Detecting Reach Deficits in Subjects With Chronic Ankle Instability. Journal of Athletic Training. 2002;37(4): 501–506.

Agility: The T- Test, as described by Semenick, was used to assess agility (Figure 4) [11]. Each subject performed two trials of the T-test and their best score was recorded. The reliability of this test has been established by previous authors [83].

Figure 4 The T-test.

Subjects start at point A. On command, they sprint forwards to point B, then side shuffle to point C, across to point D, then back to point B, then sprint backwards back to point A. Subjects must pass each cone with their leading leg and touch the base of each with their trailing leg. Subjects' feet may not cross as they side shuffle between points B, C and D.



Subjective Reports: Subjective information about the subjects' level of ankle function with daily activities and sport performance was solicited through the Foot and Ankle Disability Index (FADI) and the FADI Sport, a questionnaire designed to assess limitations in function secondary to foot and ankle injuries and conditions (Appendices B and C) [84]. The FADI focuses on activities of daily living, while the FADI Sport assesses higher-level activities related to sport performance. Each item on the FADI and FADI Sport is scored from 0 to 4. The total point value of the FADI is 104 whereas the FADI Sport is 32. The two subscales were scored separately and reported as a percentage, with 100% indicative of no dysfunction. Hale and Hertel found the FADI and FADI Sport to be reliable and sensitive measures in young, active adults [84].

3.3 Agility Program

The agility program designed for this study was based upon contemporary agility training concepts and protocols, with a focus on soccer-specific movement patterns. The program consisted of standard multidirection exercises often utilized by a soccer team including drills involving forward, backward, lateral, and diagonal movement and quick direction change. Subjects were given comprehensive written instructions with detailed descriptions of the components of their agility program, including exercise volumes and exercise progression over the course of the season (Appendix D). All subjects were given the same agility program. Proper technique and execution of the exercises was strongly emphasized in order to facilitate awareness of limb position and anticipatory control. Subjects were instructed not to wear any external ankle supports during their agility program. Subject's were instructed to perform their fifteen-minute agility training program two to three times per week and were given forms on which to document the frequency with which they performed the program throughout the study.

3.4 Procedure

All study participants were screened by the study physiotherapist to detail their ankle sprain history and to assess for any factors or conditions that would preclude their involvement as per the exclusion criteria. The study physiotherapist was an orthopaedic physiotherapist with advanced training in manual therapy and sports therapy. Once accepted into the study, subjects completed the series of tests outlined above to generate their baseline data.

The study design was as follows: While three teams were recruited for participation in the study, one team withdrew as was previously described, thus the study was completed with only two teams. The Experimental Team performed the agility training program in the Nike Free Trainers. This team was tested towards the end of their pre-season period (week 0), and then tested again at the completion of their competitive season (week 12). The Control Team had no changes to their regular training regime. This team was tested only at the end of their competitive season (week 12). All subjects from both teams were given a log to complete in which they documented their training and playing hours throughout the season (Appendix E). The Experimental Team also used this log to record their compliance with the agility training program.

For the purposes of the study, an acute ankle ligament injury was defined as any injury occurring during participation in a scheduled soccer training session and/or game that involved the ligaments of the ankle joint complex (talocrural, subtalar or inferior tibiofibular joints) and forced the subject to refrain from or modify their normal participation for one or more days. This definition is commonly used in ankle sprain literature. Any athlete sustaining an ankle injury during the course of the study was advised to complete an Ankle Injury Questionnarie (Appendix F) within twenty-four hours of their injury and to arrange an assessment with the study physiotherapist within forty-eight hours of their injury. These assessments were intended to document salient features of the mechanism of injury and clinically assess the grade and type of ankle injury (Appendix G). The standard clinical ligament stress tests of the inferior tibiofibular, talocrural and subtalar ligaments were performed. The subject was also asked to complete the FADI and FADI Sport at this time. The twenty-four and forty-eight hour timeframes were used so as to maximize the subjective and objective data obtained post-injury. Post-ankle injury, subjects were contacted by telephone to determine the time frame between injury and return to training/competition. This collection of information would allow us to look at the effect of the intervention within certain subgroups (e.g. in those who sustained contact versus non-contact ankle sprains).

Because of their late entry into the study, ankle injuries sustained by the Control Team could not be managed as per the original study procedures described above. Instead, only retrospective information regarding ankle injuries sustained by members of the Control Team could be collected. If a subject from either team sustained an ankle injury or any other significant injury that could affect their test performance, they were excluded from subsequent testing sessions.

3.5 Statistical Analysis

In addition to descriptive statistics, paired t-tests were performed for comparison of ankle strength, ankle strength ratio, static balance, dynamic balance and subjective report measures from the pre-season test to the post-season test. Only the two sets of scores generated by the Experimental Team were analyzed. A total of 29 comparisons were made; therefore, to offset the higher probability of obtaining a type I error, the Bonferroni corrected alpha used for significance in this study is 0.002. Trends are suggested at p-values of <0.05.

Pearson r was used to generate test-retest reliability data for the measures of ankle strength, static balance and dynamic balance used in this study.

CHAPTER 4. RESULTS

Thirteen players from the Experimental Team A completed the baseline pre-season testing session. The average age of the subjects was 20 (range 18 – 22 years of age). While ten of the thirteen subjects reported a history of at least one previous ankle sprain, they had high average scores on the Ankle Injury Questionnaire (2.5 out of 6, where 0 indicates no ankle complaints) and FADI and FADI Sport (both 98%, where 100% indicates no ankle complaints), indicating a high level of ankle function.

Post-season test scores are available for seven of the athletes from this group. Six players were not included in post-season test data, one because of a recent ankle injury, and the other five either because they suffered an unrelated injury during the course of the season, or because they did not attend their requisite post-season testing session.

As a result of the aforementioned modifications to the study design, it was not appropriate to perform statistical analysis related to the initial study purposes related to ankle sprain incidence and severity. For the seven players from the Experimental A Team that completed both the baseline and post-season testing a statistically significant improvement in dynamic balance was seen in the anteromedial reach direction in left leg standing (p=0.001) (Table 4). A positive trend was noted in inversion:eversion strength ratio of the right leg (p=0.042), and in five of the eight reach directions of the SEBT.

Table 1. Experimental A Team Pre-test, Post-test Comparison

Test	Significance
Inversion: Eversion Right leg	0.042 **
SEBT: Right leg – lateral reach	0.031 **
SEBT: Right leg – posterolateral reach	0.012 **
SEBT: Right leg – anteromedial reach	0.003 **
SEBT: Left leg – lateral reach	0.003 **
SEBT: Left leg – posterolateral reach	0.004 **
SEBT: Left leg – anteromedial reach	0.001*

*Indicates a statistically significant finding, where p<0.002

**Indicates a finding suggestive of a trend, where p<0.05

Test-retest reliability results for the three main measures of ankle function are presented below. This was done prior to the commencement of the main study with a small group of healthy subjects (N = 15). The data presented below reflects comparisons of performance on Trials 1 and 2 versus Trials 3 and 4.

Table 2. Reliability - Ankle Inversion and Eversion Strength Testing

Test	Pearson Correlation	Significance
Inversion	.851**	.000**
Eversion	.681**	.005**

** Indicates a statistically significant correlation at the 0.01 level

Table 3. Reliability - Static Balance Testing

Test	Pearson Correlation	Significance
Static balance eyes open	.904	.000**
Static balance eyes closed	.605	.017*

** Indicates a statistically significant correlation at the 0.01 level
* Indicates a statistically significant correlation at the 0.05 level

Table 4. Reliability - Dynamic Balance Testing

Test	Pearson Correlation	Significance
Dynamic balance – Anterior reach	.712	.003**
Dynamic balance – Anterolateral reach	.908	.000**
Dynamic balance – Lateral reach	.972	.000**
Dynamic balance – Posterolateral reach	.955	.000**
Dynamic balance – Posterior reach	.894	.000**
Dynamic balance – Posteromedial reach	.845	.000**
Dynamic balance – Medial reach	1.000	.000**
Dynamic balance – Anteromedial reach	1.000	.000**

** Indicates a statistically significant correlation at the 0.01 level

CHAPTER 5. DISCUSSION

The primary objective of this study was to determine if agility training with the Nike Free would reduce the incidence and severity of ankle sprains. As a result of the noncompliance from the subject teams and the resultant changes that had to be made to the design as the study progressed, statistical analysis and interpretation were compromised. Pre-test, post-test data was generated only for seven subjects in the Experimental Team. Because of their late start, only one set of testing data was available for the Control Team, and this was gathered at the end of the study. Because of the withdrawal of the third team, there was no intervention control team (e.g. agility training program performed in regular shoes). For these reasons, attempts at statistical analysis pertaining to the primary research questions regarding the effect of agility training with the Nike Free Trainer on ankle sprain incidence and severity were not feasible.

As pre-test, post-test data was available for some of the subjects in the Experimental Team, limited statistical analysis was possible within this group. Unfortunately a large number of subjects from this team were unavailable for the post-test, largely due to unrelated injuries, or to their failure to attend their requisite post-season testing session. In light of the limited data available, one would be remiss to make firm recommendations based on data generated in this study. Still, discussion about the trends seen in this study is warranted.

While there was only one variable that showed a statistically significant improvement over the course of the study, a positive trend was repeatedly seen in the area of dynamic balance. A trend towards improved performance in the lateral, posterolateral and anteromedial directions with both the right and left stance legs was noted. A statistically significant difference was seen in the anteromedial reach direction in left stance.

As dynamic balance is fundamental for safe and efficient performance of a multi-directional sport like soccer, the trend towards improved dynamic balance post-intervention is a promising one. Still, because of the lack of data from an intervention control group, it is unknown whether these changes can be attributed to the Nike Free Trainer, the agility training program, or a combination of these two factors. Also, with the lack of both pre-season and post-season data from the Control Team, it is even more difficult to ascertain the source of these trends.

Notwithstanding, the trends of improved dynamic balance in the Experimental Team are still of interest. Considering the shift in ankle sprain mechanism paradigm towards the proprioceptive theory, the suggestion that an ankle sprain prevention program may enhance dynamic balance is promising. Dr. Bruggemann's unpublished studies on training with the Nike Free support the notion that agility training with this shoe appears to have a positive effect on dynamic balance As compared to the often-published static balance tests, it has been suggested that dynamic balance tests may provide a more accurate reflection of lower extremity function and motor control deficits post-injury, particularly in an athletic population [85]. It is also suggested that impairments in dynamic single leg balance in the athletic population may be a significant risk factor for initial injury or re-injury following rehabilitation [87]. With respect to ankle sprains, dynamic balance has been cited as one of the impairments that most significantly contribute to the development of CAI, and that rehabilitating dynamic balance may help in the prevention of CAI [86].

Reliability testing was performed on a number of the measures used in this study. As the study designed necessitated that these measures be used in a clinical setting, it was important to use measures that would be both sensitive enough to assess the desired variables, and realistic enough for use in the field. While reliability data had been previously generated for the testing protocols chosen, because of their clinical nature, it was felt that test-retest reliability should be reestablished prior to the study commencement. The ankle strength, static balance and dynamic balance protocols were selected as it was felt that they had a greater potential for operator error as compared to the T-test. It should be noted that the reliability testing was done with healthy normal subjects, thus generalizing these results to a population of soccer players with a history of ankle sprains should be done with due caution.

While the static balance testing protocol used was based on previous studies, some modifications were made to ensure that the test would be challenging enough for our subject pool, in order to best dichotomize those with and without static balance issues. This included testing on a foam surface with both the eyes open and eyes closed, as well as defining an infraction as a loss of the start position. Previous studies have defined an infraction as the subject touching their foot down to the floor; however, it was felt that this would not be a strict enough guideline for this subject pool. As this specific testing protocol was a novel one, test-retest reliability needed to be established, and yielded value of 0.90 and 0.61 for the eyes-open and eyes-closed tests respectively (Table 3).

Previous studies by Burns et al on twenty-five healthy controls reported intraclass correlation coefficients of 0.95 for foot inversion and 0.88 for foot eversion strength test-retest reliability [75]. This protocol was used as the model for the reliability study, as well as the main study. Our reliability study generated Pearson correlation values of 0.85 and 0.68 for inversion and eversion strength respectively (Table 2). Kinzey and Armstrong reported intraclass correlations coefficients of 0.67 to 0.87 for the SEBT, generated by testing only the anteromedial and posteromedial reach directions [81]. Hertel et al studied intratester reliability of all reach directions and reported intraclass correlation coefficients of 0.78 to 0.96 over a two day period [80]. Our reliability testing generated values ranging from 0.71 to 1.0 for the eight reach directions (Table 4).

The results of this study were unfortunately compromised by weakness in its design, secondary to subject factors. For this reason, it was not possible to accurately answer the primary research questions. In order to truly ascertain the effect of agility training in the Nike Free Shoe in this population, the study must be repeated with strict adherence to the initial study design. There must be three participant teams as per the original design, and all subjects and teams must fulfill all the requirements of the study, including participation in all testing sessions at their scheduled time. If this study is repeated, there are various factors that should be considered in help improve subject compliance.

The three month timeframe for pre-season training with the Nike Free shoe used in this study was based upon Bruggemann's 2005 study, which was the only data available at the time that this study commenced. Based on Bruggemann's 2007 study, it appears that a three-week training period may be a sufficient time frame in which to generate a training effect. Reducing the pre-season training period from three months to three weeks, and thus reducing the study time frame from twenty-two weeks to thirteen weeks should greatly improve subject compliance.

In observing the team dynamics in all of the teams approached for participation in this study, the greatest compliance was garnered from teams in which the coach was enthusiastic and fully supportive of the study, and in which the coach had a large influence upon the action and behaviour of his athletes. In addition, greater compliance was noted in teams that allowed investigators to communicate directly with the subjects, as opposed to those that mandated that all communication had to be done through the coaches. Direct communication with the subjects helps to ensure that they receive all updated information regarding testing times and locations, and allows them to contact the session. These observations should be taken into account during recruitment and implementation should this study be repeated.

Modifying the subject demographics may also help to improve compliance. Because coaches often have greater influence over athletes of a younger age group, targeting high school aged athletes may help to improve compliance. While there does not appear to be any scientific literature to support this notion, coaches experienced with both high school and university aged athletes have supported this theory. The literature does suggest that injury incidence responses to prophylactic balance training programs are similar between paediatric and adult athletes; however, it has also been noted that more research in this area is needed due to the limited volume of paediatric sports injury literature [89]. Using female as opposed to male subjects may also help to improve compliance. Again, the notion of greater coach influence over female athletes has been suggested by coaches experienced in working with both male and female athletes, but there does not appear to be scientific literature to support this theory. The literature does shown that there is no statistically significant difference in soccer injury incidence and ankle sprain incidence between male and female athletes at both the high school and college ages [90,91,92].

A larger sample size is needed to increase the likelihood of highlighting significant differences should they exist. A larger study would also allow for better analysis of whether or not training effects were seen in those with and without a history of CAI. Further, a larger sample size would help to reduce the effect of the data lost as a result of the subjects who sustained unrelated injuries over the course of the study and thus were unable to participate in subsequent testing sessions. Due to the nature of soccer, it is inevitable that players will be injured over the course of a season. In this study, nearly one quarter of the subjects in the Experimental Team did not complete the post-study testing session due to unrelated injury. Such a loss becomes even more significant when the group consists of only thirteen subjects.

The value in repeating the study with the full complement of tests used in this study is questionable. The reliability data generated for the eversion ankle strength tests was only of fair strength. This may be due to the relatively more difficult time that the subjects had in performing an isolated contraction of the ankle evertors, as the tendency by many was to recruit their hip abductors to assist in the motion. Based on the data generated by Bruggemann's two studies, as well as based on the proposed mechanics of the Nike Free, it would seem that if any strength changes are likely to be seen post-intervention, they would likely be changes in foot intrinsic strength as opposed to ankle invertor and evertor strength. As such, including a test of foot intrinsic strength and omitting the ankle inversion and eversion strength measurements would be advisable in future repeats of this study. Unfortunately, to date, there does not appear to be a valid and reliable clinical test of foot intrinsic strength.

The reliability data for the eyes-closed static balance test was also only of fair strength. While the test certainly appeared to have succeeded in being difficult enough to highlight impairments in this group of highly-trained athletes; there was a large variance in performance of this test, and the fact that it was non-instrumented may have left us unable to accurately represent the performances of our subjects. As such, it is questionable whether it would be appropriate to include the same non-instrumented static balance tests in future studies. Emery states that the relevance of static balance testing to the functional dynamic nature of sporting activity is largely unknown [87]. Specific testing of joint position sense would be a worthwhile substitution for the static balance test; however, at present, there is a lack of valid and reliable tests of joint position sense that would have been appropriate for the clinical nature of this study.

The questions surrounding the proper definition and appropriate assessment of agility leads one to question whether or not it would be appropriate to include our agility test in future studies. Sheppard and Young state that many 'agility' tests do not incorporate any decision making or reactive skill and thus, would be more appropriately termed as 'change of direction speed tests' [88]. The T-Test used in this study would certainly fall into this category. In light of this lack of agreement in the area of agility, researchers have called for the development of valid and reliable tests that challenge the multiple facets of agility. In the interim, should this study be repeated, the appropriate step may be to use the T-Test, calling it a test of 'change of direction speed', or perhaps to omit the test altogether until scientific consensus is reached.

Limb dominance was not recorded in this study. Interestingly, the positive effects of the intervention on dynamic balance was seen in both the right and left legs in the Experimental group. Previous works state that studies to date have not demonstrated a difference in balance in the dominant versus the non-dominant legs [87]. Still, should this study be repeated, information regarding the subjects' dominant leg should be recorded.

5.1 Summary and Recommendations

As a result of subject non-compliance issues, this study is unable to answer the question of whether agility training with the Nike Free shoe results in a reduction in ankle sprain incidence and severity. Despite this, a trend towards improvements in dynamic balance was noted in those who performed the agility training program in the Nike Free. To better understand the relationship between agility training in the Nike Free shoe, ankle sprain prevention and dynamic balance, this study should be repeated with some modifications to its' design to facilitate better subject compliance.

The trends towards improved dynamic balance noted in this preliminary study leads one to question exactly how agility training in the Nike Free shoe may affect dynamic balance. Changes in proprioception, local muscle recruitment/patterning, control of lower limb position and/or proximal stabilizer recruitment could all be factors in improved dynamic balance and would all be interesting variables to assess in future studies. Considering the potential effect of agility training with the Nike Free shoe on dynamic balance, it would be interesting to extrapolate the study concept to investigate the effects on other injuries related to dynamic balance deficits of the lower extremity such as tibialis posterior tendinopathy, plantar fascitis, anterior cruciate ligament injuries and iliotibial band friction syndrome.

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APPENDIX A

Functional Instability Index

- ANKLE INJURY QUESTIONNAIRE -

Name_________________________ Date____________

Please circle either Yes or No for the following 6 questions

Have you ever sprained your ankle?	YES	NO
Does your ankle ever feel unstable while walking on a flat surface?	YES	NO
Does your ankle ever feel unstable while walking on uneven ground?	YES	NO
Does your ankle ever feel unstable during recreational or sport activity?	YES	NO
Does your ankle ever feel unstable while going up stairs?	YES	NO
Does your ankle ever feel unstable while going down stairs?	YES	NO

APPENDIX B

FADI

Subject Code:___________________________ Date:_____________

Please answer every question by circling the one response that most closely describes your condition within the past week. All questions pertain specifically to how your ankle(s) affects your ability to perform activities listed.

Standing	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking on even ground	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking on even ground without shoes	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking up hills	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking down hills	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Going up stairs	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Going down stairs	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking on uneven ground	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Stepping up & down curves	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Squatting	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Sleeping	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do

FADI con't

Coming up on your toes	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking initially	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking 5 minutes or less	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking approx 10 minutes	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Walking 15 minutes or more	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Home responsibilities	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Activities of daily living	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Personal care	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Light to moderate work (standing, walking)	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Heavy work (pushing/pulling climbing carrying)	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Recreational activities	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do

General level of pain	No Pain	Mild	Moderate	Severe	Unbearable
Pain at rest	No Pain	Mild	Moderate	Severe	Unbearable
Pain during your normal activity	No Pain	Mild	Moderate	Severe	Unbearable
Pain first thing in the morning	No Pain	Mild	Moderate	Severe	Unbearable

APPENDIX C

FADI Sport

Subject Code:______________________________ Date:_____________

Please answer every question by circling the one response that most closely describes your condition within the past week. All questions pertain specifically to how your ankle(s) affects your ability to perform activities listed.

Running	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Jumping	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Landing	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Squatting & stopping quickly	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Cutting, lateral movements	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Low-impact Activities	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Ability to perform activity with your normal technique	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do
Ability to participate in your desired sport sport as long as you would like	No Difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do

APPENDIX D

Agility Training Program

GENERAL INSTRUCTIONS:

- Safety is of the utmost importance – please:

Do not perform any drill if you do not feel safe, stable & comfortable with it.
Monitor your speed – you must be **in control** during all drills.
Be mindful of field conditions & make adjustments as necessary.
Be mindful of your level of fatigue & make adjustments as necessary.
Report any problems or discuss any questions with the investigators immediately.

-Please **do not** use external supports (ankle taping or bracing) during your agility training program – the goal of these exercises is to improve the strength and control of your muscles & use of external supports will hamper that process.

-Focus on technique rather than speed – all drills must be **purposeful & controlled**. Focus on a **'neutral' foot** & ankle position (not rolling too far inwards or outwards). Focus on your foot position both when your foot is on the ground, as well as when your foot is in the air and preparing for the next contact with the ground. Focus on proper athletic posture throughout your body during all drills – your body should move as a unit from head to toe (e.g. no reaching, overstriding, collapsing)

-Stretch when you're finished to reduce post-exercise soreness and prevent overload injuries. Focus on: calves, sole of foot, hamstrings, gluteals, quads/hip flexors, lower back. Pictures of sample stretches for these muscles groups are attached. Feel free to personalize your stretching program as you see fit.

-Attached is your agility training program for the 1st 3 months of the study. The program should take you 15 minutes and should be performed 3 times per week. You will receive the agility training program for the final 3 months of the study at your midterm physiotherapy assessment

OWN SHOE GROUP:

You **must** wear proper athletic footwear. Cross-trainers with a low heel height are recommended. Please do not wear your studded soccer boots or athletic shoes with a high heel height.

NIKE FREE GROUP:

In the week prior to the official start of your agility training program, allow your feet to get accustomed to the Nike Free's by:

- walking in the Free's, gradually increasing wearing time as your feet adapt to the shoes.
- once you're comfortable walking in the Free's, wear them for some short, easy jogs on the grass (up to a maximum of 10-15 mins)

Throughout the study, respect the level of support provided by the Nike Free's. They are not the same as your soccer boots or running shoes** - please make the appropriate adjustments to the speed and aggression of your movements **

WEEK 1-3	Warm-up: - forward run x 2 lengths - backward run x 2 lengths - lateral shuffle x 2 lengths - 2x 30 secs each: mini jacks – doubles - singles boxer - 3 stage skier – 3 stage Slalom run x 4 lengths (loose curves, easy) Figure 8's x 3 each direction (loose, easy) Stretch
WEEK 4-6	Warm-up Runs & lateral shuffle as above 2 x 20 secs mini jacks as above 1 x 20 secs each: boxer – 3 stage - 2 stage skier – 3 stage - 2 stage Slalom run & Figure 8's as above – tighter, faster Carioca x 2 lengths - easy Stretch
WEEK 7-9	Warm-up: Runs, laterals as above 1x 20 sec eyes open + 1 x 20 sec eyes closed: - mini jacks doubles - mini jacks singles - boxer 3 stage - skier 2 stage Slalom run x 2 lengths - tighter, faster Figure 8's x 2 each direction -tighter, faster Carioca x 2 lengths - faster Ladder runs x ½ length each: - forwards - backwards - lateral – to right & left - ins & outs – to right & left Stretch

WEEK 10-12	<u>Warm-up:</u> Runs, lateral as above 3 x 20 secs random combination of mini jacks, boxer and skier (*shadowing*) Figure 8's as above Carioca as above – faster Ladder runs as above Zig zags – 2 lengths forward - 2 lengths backwards <u>Stretch</u>
WEEK 13-15	<u>Warm-up:</u> as above Figure 8's x 1 each direction- tighter, faster Ladder runs as above T-runs 3x (easy) Zig zags – as above w/ random direction change (* shadow*) Perturbations – in running stance – 2 x 20 secs per leg <u>Stretch</u>
WEEK 16-18	<u>Warm up:</u> as above Box runs 2x each direction T-runs as above - faster Zig zags as above Lateral shuffles with random direction change (*shadowing*) – 2 x 20 secs Perturbations as above <u>Stretch</u>

WEEK 19-21	Warm up: as above Zig zags as above – 1 each Box runs 2 x 20 secs with random direction change (*shadowing*) Lateral shuffles as above Idle and sprint x 2 lengths Perturbations x 20 secs each – 1x per leg in running stance 2x per leg in lunge stance Stretch
WEEK 22-24	Warm-up as above Zig zags as above Box runs as above – 1 x 20 secs Lateral shuffles as above – 1 x 20 secs Idle & sprint as above w/ random changes (*shadowing*) Perturbations as above x 1 per position Stretch

Agility Training Program Instructions

-Most exercises are described as being performed using either the full length or half the length of a soccer field.

- Exercises are progressed every 3 weeks. Start any new exercise slowly. Over each 3 week period, as your comfort and confidence level increase, progress the speed and aggression of the drills.

-"Shadowing" drills incorporate unexpected change in direction or activity. They will be done in pairs or small groups, during which one player initiates the movement and the other must copy the movements of his partner.

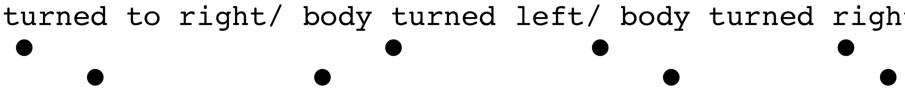
DESCRIPTION OF DRILLS:

<u>Lateral shuffles</u>
Side stepping, no crossing of the feet

<u>Mini jacks</u>
Like mini jumping jacks – feet apart then feet together

<u>Boxer</u>
Like a boxer stance, with one foot slightly ahead of the other & body turned to one side such that shoulders remain square over the hips. Always double hop in one stance before changing to the next stance. Entire body turns as a unit.

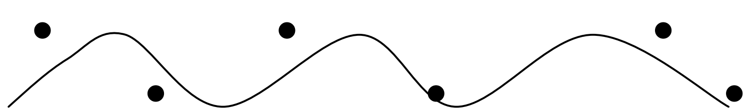
Body turned to right/ body turned left/ body turned right……



<u>Skier</u>
One foot slightly in from of other, feet remain hip width apart & trunk remains pointing straight ahead through all stances.

Right ahead & left back/ left ahead & right back/ right ahead & left back…….

<u>Slalom runs</u>
As if you were running a curved line between cones (no sharp corners/cuts)



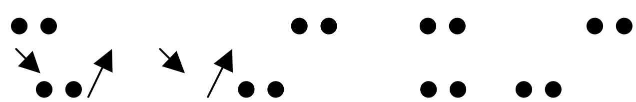
<u>Figure 8's</u>

Initially, these should take about 2/3 of the length of the soccer field, using loose and easy curves. Progress to 1/2 then 1/3 of the field, using tighter curves

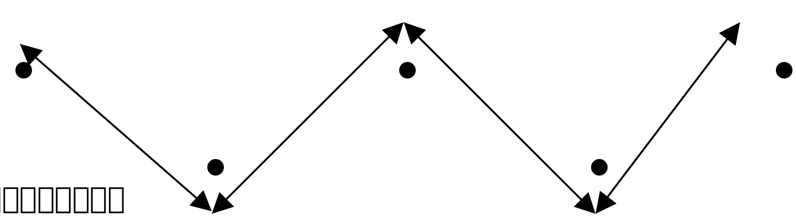
<u>Carioca</u>
Aka "grapevine". Lateral run in which one leg crosses in front of the other leg, then behind the other leg

<u>Ladder runs</u>
Imagine stepping between the rungs of a ladder on the floor – focus on quick feet, low knee drive, and weight staying on balls of feet. Pump arms quickly to keep pace.

- forwards through rungs of ladder
- backwards through rungs of ladder
- lateral: sidestepping through rungs of ladder
- ins & outs: imagine moving laterally while stepping into, then out of the rugs of the ladder



<u>Zig Zags</u>
Forwards: straight run along diagonal to each imaginary cone, then cut diagonally towards next imaginary cone
Backwards: shuffling feet (no crossing) along diagonal from one imaginary cone to the next
"Shadowing": the lead player decides where & when to make the cuts, the other players must follow their lead



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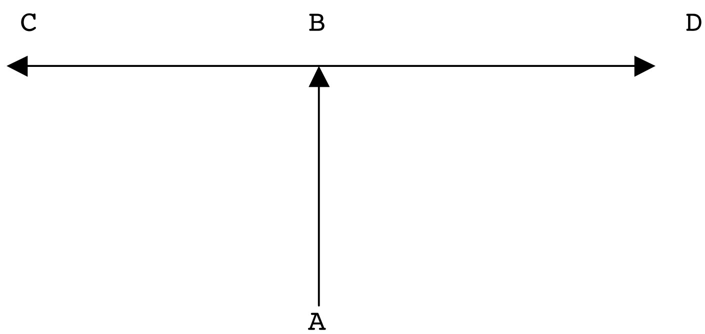
<u>Perturbations</u>
In pairs: one player <u>gently</u> taps the other at various locations, speeds & intensities to knock their partner off balance.
Running stance: standing on one leg, arms across chest, opposite hip and knee bent to 90 degree angles
Lunge stance: in lunge (split squat) position with thigh of front leg parallel to floor & heel of back foot up off floor (e.g. on ball of foot of back leg), arms across chest

T- runs

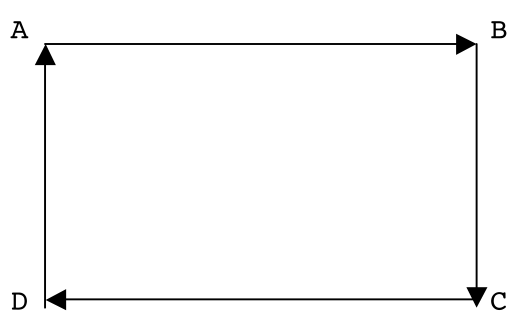
Run from A to B. Lateral shuffle from B to C (or from B to D) then back to B. Backward run from B to A. Watch the speed of your transitions, especially at point B. Distance from A to B = 1/4 of the length of soccer field; distance from C to D = 1/2 the width of soccer field



Box runs

Run from D to A. Lateral shuffle from A to B. Backward run from B to C. Lateral shuffle from C to D. Start with a box that would fill 1/4 of one half of the soccer field. To progress, make box smaller

“Shadowing” - Pair of players stand one behind the other (be sure to give each other enough room!). The front player runs a box, changing from one direction to the next randomly; the back player follows.

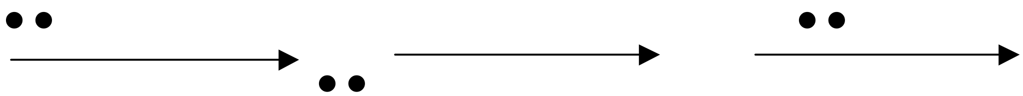


Lateral shuffles with shadowing

2 players stand facing one another. One player lateral shuffles side to side (no crossing feet), randomly changing direction; the other player must follow.

Idle and sprint

Facing an imaginary line, idle with 'mini jacks' or 'skier' for 5 seconds, then turn and sprint 5 meters down the line. Alternate types of idle, as well as the side of the line that you idle on. "Shadowing" – Pair of players face each other. One player chooses the type of idle (mini jack or skier) and dictates when to change from idle to sprint; the other player follows.



APPENDIX E

Day to Day Record

Subject Code:____________________

Use the calendar below to indicate the following:

(1) each training session (T) and approx length in minutes
(2) each game (G) and approx length in minutes
    (e.g. record a 1.5 hour training session or game as T = 90 or G=90)
(3) if in an experimental group, each day you perform your functional training program (F)

June 2006

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

APPENDIX F

Ankle Injury Questionnaire

please complete within 24 hours of your injury

Subject Code:______________________ Date of Injury:_____________

My injury occurred during a (circle one):

Training session Game Non-soccer activity

If you normally wear an ankle support (e.g. tape/brace) were you wearing it at the time of the injury (circle one): No
Yes – specify type____

Have you sprained this ankle before (circle): Yes No

Was your injury (circle one): Contact Non-contact

What type of field did your injury occur on (circle):

Grass Turf All-weather Other (specify)___________

Briefly describe how the injury happened:

PLEASE DO THE FOLLOWING:

- arrange to see a physiotherapist within the next 48 hours (refer to the list of physiotherapists affiliated with the study and choose one in your area). Please call them as soon as possible.
- bring this form with you to your physiotherapy appointment – they will take it from you.
- check with your trainer before returning to training or competition

APPENDIX G

Physiotherapist Ankle Injury Assessment

Physiotherapist:________________________________ Date:_____________

Athlete's Subject Code:____________________________________

Date of Injury: ____

Location of injury (circle one): Right Left Bilateral

Is this their dominant leg (circle one): Yes No Ambidextrous

Structure(s) involved (circle):
(if bilateral, indicate right or left when answering the next question)

Lateral collateral ligaments: ATFL CFL PTFL

Medial collateral ligaments: Anterior Middle Posterior

Inferior TibFib ligaments

Subtalar ligaments

Comments (optional):

Severity- indicate below the highest grade injury sustained (circle):

1st degree
2nd degree
3rd degree

Comments (field type, contact/noncontact, inversion/eversion MOI, contributing factors):

APPENDIX H

Consent Form

SUBJECT INFORMATION and CONSENT FORM

Title of Project: Ankle Sprain Prevention Pilot Study – The Effect of the Nike Free Shoe in Elite Male Soccer Players

Principal Investigator: Dr. Jack Taunton MD, PhD
[redacted]

Co-Investigator: Nadine Nembhard
[redacted]

Emergency Contact: Nadine Nembhard
[redacted]
Can be contacted 24 hours a day, 7 days a week

Introduction

You have been invited to take part in this research study. Your participation is entirely voluntary; therefore, it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what this research project involves. This form will tell you about the study, why it is being done and what will happen during the study.

If you wish to participate, you will be asked to sign this form. If you decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reason for your decision.

Please take the time to read the following information carefully. You may wish to discuss it with your medical practitioner, coach and/or family before making your decision.

Background

Ankle sprains are the most common form of athletic injury and the most common injury in soccer players. Time lost due to the pain and decreased function following an ankle sprain can be very costly to the success of the individual athlete, as well as to the success of his or her team.

Current theory suggests that ankle sprain treatment and prevention should be focused on approaches that improve foot and ankle strength, balance and ankle position sense, rather than on approaches that simply provide external support to the ankle like bracing and taping. The Nike Free is a specialized athletic shoe designed to mimic the challenges placed on the foot during barefoot running. In doing so, early studies have shown that training with the Nike Free shoe improves foot and ankle strength and balance. Since these factors are considered to be vital in the treatment and prevention of ankle sprains, the Nike Free shoe may have a role to play in prevention of ankle sprains.

Purpose

The purpose of this study is to investigate the effect of training with the Nike Free shoe on ankle function and the incidence of ankle sprains in elite male soccer players.

Study Procedures

The study will follow players from three teams in the CCAA through the 2006 season. There will be one control team and two experimental teams. If in an experimental groups, you will perform a specific agility-training program for 15 minutes, 3 times per week in the pre-season and 2 times per week in-season. One experimental team will use their athletic shoes during their agility training, while the other experimental team will use the Nike Free shoe. If in the control group, there will be no changes made to your training or competition schedule.

Pre-Study:
You will be screened by a physiotherapist to find out about your ankle sprain history and to determine if you have any injuries or medical conditions that would make it inappropriate for you to participate in the study. Tests will also be done to ensure that you do not have any significant ankle malalignment or ligament laxity that would make it unsafe for you to participate in the study. Your ankle will be assessed with an emphasis on ankle strength, balance and agility. You will be given 2 short questionnaires to complete which will ask for details about the current function of your ankle with daily activities. This entire pre-study screening should take 45 minutes to 1 hour.

If you are in the experimental groups, you will be shown your agility-training program and, if applicable, given your Nike Free shoes.

During the Study:
Throughout the study period, subjects in the experimental groups will complete a Training Log to document their performance of their agility- training program as well as to report any problems or concerns with their program. The Training Log will take less than 5 minutes to complete

For the purposes of the study, an ankle injury will be classified as any injury involving the ankle ligaments that forces you to withdraw from or modify your participation in your current training session/game and/or miss your subsequent training session/game. If you think that you may have injured your ankle, you will be asked to complete an injury questionnaire within 24 hours of the injury. This will take less than 5 minutes to complete and will ask for details about how the injury occurred and the location of pain. You will arrange to be assessed by one of our physiotherapists within 48 hours of the injury to determine the location and severity of the injury. The physiotherapist will give you 2 short questionnaires to complete. The assessment and questionnaires will take no more than 20 minutes.

Prior to returning to training/competition, you must be medically cleared by your team trainer. After you have returned to training/competition, you will be telephoned by the study co-investigator, Nadine Nembhard, to determine the time frame between your injury and your return to sport. This telephone interview will take less than 5 minutes.

Three months into the study, all participants will be asked to undergo a midterm physiotherapy assessment, during which your ankle strength, balance and agility will be reevaluated. You will also be asked to complete 2 short questionnaires again. This mid-term reassessment should take no longer than 30 minutes.

Post-Study:
At the end of the soccer season you will be asked to undergo one last physiotherapy assessment for reevaluation, and to complete 2 short questionnaires as described above.

Inclusions

You will be eligible to participate in this study if you are a male soccer player in the CCAA, age 18 or over.

Exclusions

You will be excluded from the study if any of the following apply to you:

- you have a significantly unstable ankle (as determined by physiotherapist assessment)
- you have recent or ongoing injuries that make it unadvisable for you to participate in the study (e.g. recent ankle sprain, knee ligament sprains/tears, recent lower limb fractures, foot deformity)
- you have a medical condition that affects your balance and/or would make it unadvisable for you to participate in the study (e.g. multiple concussions or other head injuries, neurological or vestibular system conditions)
- you are currently participating, either formally or informally, in an ankle rehabilitation program
- you are unable or unwilling to complete the agility program (if in an experimental group) to complete the required questionnaires, or to attend the required physiotherapist assessments throughout the soccer season

Risks

We request that you report any problems or unusual symptoms to the Investigators, as well as to your coach/trainer immediately. Efforts will be made to structure the study in such a way as to minimize discomfort and risk. In a previous study using the Nike Free shoe during athletic training, 54% of subjects using the Nike Free shoe had no pain while 42% of them noticed muscle soreness in the foot and ankle area for an average of 2.6 days in the first week of the study. Other reports of limited pain in the ankle joint complex and moderate knee pain and shin pain were reported in those training with the Nike Free as well as in those training in their regular shoes. These reported pains did not require any subject to withdraw from the study.

Remuneration

As a subject in this study, you will receive a free pair of Nike Free shoes. Half of those in the experimental group will receive them at the beginning of the study, while the remainder of those in the experimental group, as well as all of those in the control group, will receive them at the end of the study. Nike is sponsoring the study and supplying shoes for all the participants.

Benefits

The experimental group subjects may decrease their risk of ankle sprain during the season, thus reducing the pain, loss of function and loss of training and playing hours associated with this common soccer injury. As a previous study on the Nike Free shoe reported improvements in balance and ankle and foot muscle strength, the experimental group athletes may also experience these beneficial effects over the season of training with the Nike Free shoes.

Confidentiality

Data collected during this study will be kept confidential. All data and documents will be identified by a code number and stored in a locked filing cabinet. Only the investigators listed on this consent form will have access to the data. Should this data be published or presented at a conference, it will be done in such a way that it is impossible to identify individual subjects. No information that discloses your identity will be released or published without your specific consent to the disclosure. Research records identifying you may be inspected in the presence of the Investigator by Health Canada, and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices. These records will be stored in a locked room that only Nadine Nembhard and Dr. Jack Taunton will have access to. All files pertaining to this study will be stored on a computer that is password protected.

Contact

Should you have any questions about the procedures or your involvement in this study, please contact the Investigators at the phone numbers listed above. Please note that you do not waive any of your legal rights by signing this consent form. If you have any concerns or questions about your rights as a research subject, you may contact the R[redacted]t Information Line in the UBC Office of Research Services at [redacted].

Consent

By signing this consent form you acknowledge that you have read and understood all six pages of this consent form, and will voluntarily consent to participate in this study. You also admit to having received a copy of this consent form, by signing below. You will receive copy of the signed and dated consent form to retain for your records. Please note that Nadine Nembhard will act as the delegated representative of the Principal Investigator, Dr. Jack Taunton.

I understand my participation in this study is voluntary, and I retain the right to withdraw from the study at any time without consequence. I have read and understood this consent form and have received a copy for my own records. I consent to participate in this study.

Subject name ____________________________

Subject signature ____________________________ Date ________________

Witness name ____________________________

Witness signature ____________________________ Date ________________

Investigator name ____________________________

Investigator signature _________________________ Date ________________

The University of British Columbia
Office of Research Services,
Clinical Research Ethics Board – Room 210, 828 West 10th Avenue, Vancouver, BC V5Z 1L8

Certificate Full Board Approval: Amendment

Clinical Research Ethics Board Official Notification

PRINCIPAL INVESTIGATOR	DEPARTMENT	NUMBER
Taunton, J.E.	Family Practice	**C05-0416**

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT
UBC Campus
CO-INVESTIGATORS:
Nembhard, Nadine, ; Wauthy, Peter,
SPONSORING AGENCIES
Unfunded Research
TITLE:
The Role of the Nike Free Shoe in Ankle Sprain Prevention in Elite Male Soccer Players

APPROVAL DATE (yy/mm/dd)	TERM (YEARS)	AMENDMENT:	AMENDMENT APPROVED:
05-09-08	1	Protocol Reference #2, Version #2 dd 4 Oct 2005; Athlete Letter of Initial Contact Reference #3a, Version #2 dd 4 Oct 2005; Coach Letter of Initial Contact Reference #3b, Version #2 dd 4 Oct 2005; Subject Consent Form Reference #4, Version #2 dd 4 Oct 2005; Questionnaires Reference #5, Version #2 dd 4 Oct 2005	**03 January 2006**

CERTIFICATION:

In respect of clinical trials:

1. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations.
2. The Research Ethics Board carries out its functions in a manner consistent with Good Clinical Practices.
3. This Research Ethics Board has reviewed and approved the clinical trial protocol and informed consent form for the trial which is to be conducted by the qualified investigator named above at the specified clinical trial site. This approval and the views of this Research Ethics Board have been documented in writing.

The amendment(s) for the above-named project has been reviewed by the University of British Columbia Clinical Research Ethics Board, as presented in the documentation, and the accompanying documentation was found to be acceptable on ethical grounds for research involving human subjects

The CREB approval period for this amendment expires on the one year anniversary date of the CREB approval for the entire study.

[redacted]

Approval of the Clinical Research Ethics Board by one of:
Dr. Gail Bellward, Chair
Dr. James McCormack, Associate Chair