Biomechanical and comfort analyses on the use of commercial insoles while walking and running

by

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A thesis submitted to the graduate faculty

in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

Major: Kinesiology

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2022

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NOMENCLATURE

PFPS	Patellofemoral Pain Syndrome
MTSS	Medial Tibial Stress Syndrome
ITBS	Iliotibial Band Syndrome
PFJ	Patellofemoral Joint
ITB	Iliotibial Band
TFL	Tensor Fasciae Latae
LFE	Lateral Femoral Epicondyle
ASIS	Anterior Superior Iliac Spine
PSIS	Posterior Superior Iliac Spine
ATL	Achilles Tendon Load
PFM	Plantar Flexion Moment
ATMA	Achilles Tendon Moment Arm
GRF	Ground Reaction Force

ACKNOWLEDGMENTS

First and foremost, I'd like to thank my major professor, Dr. Jason Gillette, for taking me on as a graduate student and for the opportunities he has provided me in both research and teaching roles over the past two years. I am grateful for the continued support and guidance that he has provided throughout this process. Thank you to my committee members Dr. Tim Derrick and Dr. Gary Mirka for their time, input, and support throughout this project. Lastly, thank you to Dr. Mark Mendeszoon and Achilles Run Shop for their enthusiasm and donation of insoles that made this study possible.

I've been incredibly blessed to have been shown the importance of great academic mentorship not only once, but twice, in my life. I would also like to thank Dr. Scott McLean at Southwestern University who first inspired my interest in Biomechanics and whose confidence in my abilities encouraged me to further pursue my academic dreams. Under the guidance of both Dr. Gillette and Dr. McLean, I have been able to and will continue to grow, in more ways than I ever thought possible.

Finally, I would like to thank my family and friends who not only fully supported a cross-country move but actively encouraged every aspect of this journey. I will never be able to fully express how much each and every one of you means to me. And to my dog, Archie, thank you for your companionship and for making every new city feel like home. Knowing I was always coming home to your wagging tail made getting through even the longest days so much easier.

ABSTRACT

Background: Incidence rates of running injuries are high. Previous research has indicated that the use of prefabricated insoles may be beneficial for altering kinematic and kinetic patterns that cause running injuries. The purpose of this study was to evaluate how prefabricated insoles affect kinematics, kinetics, plantar pressure, and perceived comfort during walking and running.
Methods: Twenty-one (16 female, 5 male) participants walked and ran with their regular running shoes and with two types of prefabricated insoles. A motion capture system and force platforms were used to collect kinematic and kinetic data. Pressure inserts were used to collect plantar pressures, and a comfort questionnaire was used to measure levels of perceived comfort.
Results: The Currex insole reduced ankle eversion and peak midfoot pressure during walking, while reducing peak toe and average whole foot pressure during running. However, the regular running shoe was still preferred over the Currex insole by a higher percentage of participants, 55% to 35%. The PowerStep insole also reduced ankle eversion and peak midfoot pressure during walking, while reducing Achilles tendon load and ankle inversion moment during running. However, the PowerStep insole had lower comfort ratings than the regular running shoe and Currex insole. *Conclusion:* In a combined evaluation of kinematic, kinetic, and plantar pressure data with comfort scores, there was a mix of potential benefits, drawbacks, and perceptions of insole use. These conflicting results may indicate that prefabricated insoles are most likely to be beneficial when matched to an individual's biomechanical needs, comfort preferences, and intended use.

CHAPTER 1. GENERAL INTRODUCTION

Running as a sport or recreational activity has grown significantly in popularity since the 1970's (Schreeder et al., 2015). One of the biggest drawbacks to the sport that is otherwise a cost effective lifestyle medicine (Lee et al., 2017) is the likelihood of sustaining a running related injury. Incidence rates of lower extremity injuries may range anywhere from 19-79% (van Gent et al., 2007). Lower extremity injuries to the foot, ankle, calf, and knee account for approximately 75% of running injuries while injuries to the upper leg, hip and pelvis, and lower back make up the remaining 25% (Fields, 2011). Currently, specific injuries that demonstrate the highest prevalence in the sport include patellofemoral pain syndrome (PFPS), medial tibial stress syndrome (MTSS), plantar fasciitis, iliotibial band syndrome (ITBS), Achilles tendinopathy, and stress fractures/fractures (Kakouris et al., 2021).

A combination of intrinsic and extrinsic risk factors likely predispose runners to injury. Common intrinsic risk factors include runner demographics such as age and biological sex, anatomical structure, history of previous injury, muscular deficits, kinematic patterns, and kinetic patterns. The change in running demographics since the 1970's has led to a running population that is more female, older, and runs recreationally (Andersen, 2021). Female runners have been shown to have higher rates of injury to the knee and bone, while males have been shown to be more likely to develop Achilles tendinopathies and plantar fasciitis (Reinking et al., 2017; Taunton et al., 2002; Hollander et al., 2021). Age has also been associated with type of injury a runner may be more susceptible to. Older runners have a higher prevalence of injuries to the Achilles and younger runners suffer more injuries to the knee and leg (McKean et al., 2006).

Anatomical structure such as Q-angle measurement or pes cavus and pes planus foot types have been associated with greater risk of running injury. Larger Q-angles put female runners at greater risk for developing PFPS or ITBS compared to their male counterparts (Ferber et al., 2003). Similarly, those with pes cavus or pes planus foot types have been identified as being at higher risk for developing a variety of injuries. Some studies have established different injury patterns based on classification of foot type (Williams et al., 2001a; Williams et al. 2001b) while results of other studies suggest that having either arch deformity puts runners at higher risk of injury (Pohl et al., 2009; Riberio et al., 2011).

Kinematic patterns associated with high rates of running injury include excessive eversion, pronation, tibial internal rotation (TIR), hip adduction, hip internal rotation, and various degrees of knee flexion angles. It should be noted that much inconsistency amongst these variables remains across the literature suggesting that specific kinematic patterns are not universal in causing running injuries but may be more applicable to specific subpopulations. Excessive eversion and pronation of the foot has been directly linked to the development of MTSS (Okunuki et al., 2019), and stress fractures (Milgrom et al., 2007; Pohl et al., 2008). Due to the mechanical coupling of the leg and foot, calcaneal eversion can result in significant TIR leading to Achilles tendinopathies (Clement et al., 1984) and PFPS (Rodriguez et al., 2014). The mechanical coupling as a cause for PFPS and ITBS has been highly controversial throughout the literature. Many studies find that even without abnormalities in rearfoot eversion or pronation, abnormal tibial rotation is linked to both PFPS (Arazpour et al., 2016) and ITBS (Noehren et al., 2007).

Runners who display greater hip adduction have been linked to the development of PFPS (Dierks et al., 2008; Wilson & Davis, 2007), ITBS (Ferber et al., 2010; Noehren et al., 2007), and tibial stress fractures (Pohl et al., 2008; Milner et al., 2010). Still, studies remain inconclusive on these relationships between hip adduction on PFPS and ITBS (Dierks et al., 2011; Baker et al., 2010). Greater hip internal rotation has also been associated with PFPS

(Meira et al., 2011), ITBS (Ferber et al. 2003; Noehren et al., 2014), and MTSS (Yagi et al., 2003).

Kinetic patterns associated with running injuries include extension, abduction, tibial rotation, and inversion moments. Most notably, forces such as ground reaction force (GRF) and joint contact forces are often associated with the development of running injuries. Differences in maximum braking forces have been shown in runners with PFPS (Messier et al., 1991), ITBS (Messier et al., 1995), and Achilles tendinopathies (Baur et al., 2004). Excessive loading and strain on both the Achilles (Rice & Patel, 2017) and plantar fascia (Pohl et al., 2009; Johnson et al., 2020) have also been highly correlated to the development of injury.

The use of insoles and orthotics has become widely popular for the treatment or prevention of foot and knee pathologies. Both devices primarily serve to align the skeleton, improve impact cushioning, and/or provide improved comfort (Nigg et al., 1999). Prefabricated insoles have been shown to be more cost effective (Ring & Otter, 2014) and perform to at least equal standards as custom fit orthotics both biomechanically and in perceived comfort ratings (Gil-Calvo et al., 2020; Lucas-Cuevas et al., 2014b). This suggests that prefabricated insoles stand as a reasonable alternative to custom orthotics.

Prefabricated insoles effect the closed kinematic chain by adjusting excessive rearfoot eversion and pronation (Smith et al., 1986; Novick & Kelley, 1990; Majumdar et al.,2013). Insoles have been found to reduce frontal plane ankle movement in studies involving runners with PFPS (Eng & Pierrynowski, 1994) and plantar fasciitis (Sinclair et al., 2015b). However, some studies have found no significant effect between insole use and rearfoot eversion (GilCalvo et al., 2020; Nawoczenski et al., 1995, Dixon, 2007). When observing the coupling mechanism between calcaneal inversion and eversion with tibial rotation, studies have found significant relationships (Mündermann et al., 2003). However, other studies have reported no differences in ankle inversion while observing differences in tibial rotation (Stacoff et al., 2008; Nawoczenski et al., 1995). Further up the chain, insoles have also been shown to reduce the amount of hip range of motion in the transverse and frontal planes (Braga et al., 2019).

The primary variables used to evaluate kinetic effects of insoles include loading rates and peak ground reaction forces. However, results from these studies are rather inconsistent. Studies exist supporting the use of insoles to attenuate the role of impact and contact forces on running injury (Dixon, 2007; Landorf et al., 2006; Sinclair et al., 2016) while others report no or detrimental effects with the use of insoles (Mündermann et al., 2003; Sinclair et al., 2016). Other proposed kinetics changes with the use of insoles include reduced ankle inversion moment (Mündermann et al., 2003; Nigg et al., 2003) and both reductions and increases for knee external rotation moment (Mündermann et al., 2003; Nigg et al., 2003).

Perceptions of comfort have been introduced as an important factor in the successful use of insoles. Studies based on comfort have found significant decreases in frequency of injury for insole conditions which participants found more comfortable (Mündermann et al., 2001). It has also been shown that more flexible, softer products that continue to offer structural support such as a semi-rigid insole have been found to be preferred by users than hard or rigid insoles (Braunstein et al., 2015; Mündermann et al., 2002). One measurement that has been used to quantify the comfort of insoles is plantar pressure distribution of the foot. This relationship remains unclear as studies have found correlations between plantar pressure and comfort (Chen et al., 1994; Wegener et al. 2008) while others show lack of evidence for such correlations (Jordan & Bartlett, 1995; Braunstein et al., 2015).

No study known by the authors to date has performed a biomechanical analysis of prefabricated insoles based on the combined evaluation of kinematic, kinetic, and plantar pressure data with perceived comfort scores. In order to fill the gap in knowledge participants in this study will be assessed based on both quantitative kinematic, kinetic, and plantar pressure data with the added qualitative assessment of perceived comfort. It is hypothesized that prefabricated insoles will provide improved subjective comfort compared to the baseline running shoe. When comparing types of prefabricated insoles, it is hypothesized that a softer more flexible insoles such as Currex will result in improved comfort and beneficial biomechanical changes compared to more rigid insoles such as PowerStep. Finally, increases in perceived comfort are hypothesized to be associated with beneficial biomechanical changes.

CHAPTER 2. REVIEW OF THE LITERATURE

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Modified from a manuscript to be submitted to *Clinical Biomechanics*

Popularity of Running

Running as a sport has grown in popularity since the 1970's (Schreeder et al., 2015) as approximately 30 million Americans (Haberman, 2017) have taken up the sport either recreationally or for competition. The rise of the recreational runner coincided with scientific evidence aimed towards the general public of the health related advantages of long-lasting moderate physical activity (Cooper, 1968). This "running boom" led to dramatic increases in participation for distance road running events. Between 1970 and 1979 the Boston Marathon had an increase in finishers from 1,011 to 5,958. During the same period, the New York City Marathon had an even greater increase in number of finishers from 55 to 10,477 (Schreeder et al., 2015). Today, the Boston Marathon and New York City Marathon each have between 25-27 thousand finishers annually. Research continues to support the long term health benefits of running, with runners having a 25-40% reduced risk of premature mortality (Lee et al., 2017).

Change in Running Demographics

The demographics of runners have changed significantly over the past 50 years. In 1971, the average respondent to Runner's World was a 29 year old, 5'9", 145 pound male who had been running 50 miles per week for 6 years (Beverly, 2016). The first key shift in running demographics is the shift from competitive runners to recreational runners. People have chosen to participate in running as a leisure activity for a variety of reasons. Not only is running relatively inexpensive in that it doesn't necessarily require any expensive equipment or gym memberships, it can be done in practically any setting regardless of climate. Many runners mainly participate in the sport to take advantage of the variety of physical and mental benefits it provides.

A European study by Synovate (2008) reported that people are likely to start running to get fit (54%), lose weight (40%), to have fun (34%), and/or to relieve stress (35%). Another shift in demographics is that runners tend to focus on completing a race rather than competing in it (Van Bottenburg et al., 2010). This is evident by the drastic increase in finishing times. In 1986, the average marathon finishing time was 3:52:35, while in 2019 the average finishing time was 4:32:49, a difference of more than 40 minutes (Andersen, 2021). Additional recreational running events such as fun runs for charitable functions and community celebrations have continued to encourage participation in running.

Prior to the “running boom” of the 1970’s, it was widely believed that females were physiologically incapable of running long distances and that doing so could even be harmful to the female body. Women were not officially allowed to compete in either the Boston Marathon or New York City Marathon until the early 1970’s (Schreeder et al., 2015). Since then, women’s participation in distance running events has steadily increased. In 2018, the number of female runners surpassed the number of male runners in distance events from 5Ks to marathons for the first time, with 50.24% of runners being female. This is a 30% increase over a 40 year period (Andersen, 2021).

Similar to how the percentage of female runners has increased, the average age of runners has also increased. Between 1986 and 2018, the average running age increased by 4.1 years. Runners are not only having longer careers, but are starting to run at an older age. Older runners are more likely to be participating in shorter races such as 5Ks and 10Ks, which saw average increases in age of 25% (32 to 40 years) and 23% (33 to 39 years), respectively

(Anderson, 2021). Average age is also increasing in the half marathon (3%, 37.9 to 39 years) and marathon (6%, 38 to 40 years).

Epidemiology of Injury Trends in Runners

A high risk of sustaining a running related injury is one of the biggest drawbacks of a sport that is otherwise a cost effective and health promoting mode of physical activity (Lee et al., 2017). With increased participation in running, it’s reasonable to assume that the prevalence of injuries also increased. Unfortunately, systematic documentation of running injuries was rare prior to the 1970’s. Much of the early work documenting running injuries came in the form of surveys conducted by Runner’s World. Readers responded to the survey reporting any “major foot and leg injuries”, where “major” was defined as “requiring a complete layoff from running”.

The 1971 results of this survey reported the five most common injuries being knee injury (17%), Achilles tendon injury (14%), medial tibial stress syndrome (10.6%), arch injury (6.9%), and ankle injury (6.4%). By 1979, clinical injury statistics reported by the Runners Clinic of St. Elizabeth’s Hospital in Massachusetts ranked the top five most common injuries as knee injury (30.5%), heel spur syndrome including plantar fasciitis (13.5%), shin splints (10.9%), muscle pulls (8%), and Achilles tendonitis (6%) (Cavanagh, 1980). Within the span of ten years, metatarsal stress fractures and injuries to the Achilles tendon, ankle, and heel bone had decreased in incidence rates. However, knee injuries, shin splints, heel spur syndrome, and leg fractures all increased in incidence rates.

Current trends in running injuries are similar to those reported in the 70’s with the knee (25%), lower leg (20%), foot (16%), and ankle (15%) accounting for the highest rates of injury prevalence and incidence rate (Fields, 2011). These injury sites are followed by the upper leg (10%), hip/pelvis (7%), and lower back (7%). Specifically, running-related musculoskeletal injuries that demonstrate the highest prevalence proportion include patellofemoral pain syndrome (PFPS; 16.7%), medial tibial stress syndrome (MTSS; 9.1%), plantar fasciitis (7.9%), iliotibial band syndrome (ITBS; 7.9%) Achilles tendinopathy (6.6%), and stress fracture/reaction of the tibia, fibula, fifth metatarsal, navicular and/or calcaneus (5.7%) (Kakouris et al., 2021).

The incidence of lower extremity injuries associated with running varies greatly between studies and has been reported to range from 19% to 79% (van Gent et al., 2007). Incidence rates reported according to exposure of running time also has a wide range from 2.5 to 12.1 injuries per 1000 hours of running (van Machelen, 1992). This variable range of relative running injury frequencies exists partially due to the inconsistency of the definition of an injury throughout the literature. Epidemiological studies have used definitions of injuries that range from the reduction of or cessation of training, medical consultation or treatment, and/or absence from work.

Anatomy and Etiology

PFPS

The patellofemoral joint (PFJ) is formed by the articulation of the posterior portion of the patella and the trochlear surface of the distal anterior femur (Loudon, 2016). The patella is a small sesamoid bone that is located between the quadriceps tendon and the patellar tendon. The quadriceps tendon attaches the quadriceps muscles to the base of the patella, while the patellar tendon attaches the apex of the patella to the tibial tuberosity. The patella plays a role in protecting the knee joint anteriorly as well as increasing the mechanical advantage of the quadriceps muscles. Movement of the patella is also constrained by the patellar retinaculum and patellofemoral ligament.

Stress on the PFJ may be the leading cause of PFPS (Loudon, 2016), which causes pain on the anterior portion of the knee. Large compression forces are experienced within the PFJ due to force from the quadriceps muscle and the knee flexion angle. The reaction force of the PFJ directed into the intercondylar groove is formed by the sum of the force vector of the quadriceps tendon and the force vector from the patellar tendon (Whiting & Zernicke, 2008). It's commonly thought that increased and repetitive joint stress leads to the subsequent wear of the articular cartilage. Stresses leading to PFPS are likely influenced by altered lower extremity kinematics including abnormal anatomy or alignment, abnormal patellar tracking, movement/loading of the lower kinetic chain, muscular deficits, and overuse (Powers, 2003).

ITBS

The iliotibial band (ITB) is a thick band of fascial tissue that spans from the iliac crest to the lateral tibial tubercle and runs down the lateral portion of the thigh along the linea aspera. Proximally, it connects to the iliac crest, tensor fasciae latae (TFL), and gluteus maximus. Distally, the ITB crosses the knee and inserts onto Gerdy's tubercle. The proximal portion serves as a hip stabilizer by providing resistance to hip adduction and internal rotation (Fredericson et al., 2000), while the distal portion resists knee external varus moments and internal rotation of the tibia (Hamill et al., 2008).

ITBS causes pain on the lateral portion of the knee and is one of the top two leading causes of knee pain in runners along with PFPS. There are multiple theories regarding the etiology of ITBS including friction of the ITB on the lateral femoral epicondyle (LFE) and/or compression of the distal attachment (Charles and Rodgers, 2020). The friction theory proposes that with repeated flexion and extension of the knee, the distal portion of the ITB passes over the LFE at approximately 30 degrees of flexion during foot-strike and early stance. Orchard et al. (1996) described this as the "impingement zone" where eccentric contraction of the TFL and gluteus maximus that decelerates the leg causes large amounts of tension in the ITB. The second theory proposes that the large amounts of tension created during the "impingement zone" causes compression of the fatty layer between the ITB and LFE as opposed to a friction buildup (Fairclough et al., 2007).

MTSS

MTSS is often generally classified as shin splints. However, the term shin splints acts as an umbrella term showing lack of consensus on the definition of the injury, causes, and anatomical source of pain. This has led to the recommendation of many researchers to instead use terms that are clinically correct, specific, and useful (Batt, 1995). Still, MTSS continues to be widely defined across the literature.

The development of MTSS in runners is largely thought to be caused by overuse with some indications for other intrinsic and extrinsic factors. Pain caused be MTSS is described as being exercise induced and localized to the posteromedial side of the mid to distal tibia (Whiting & Zernicke, 2008). Substantial controversy still exists about the anatomical source(s) and biomechanical development for MTSS. Broadly, MTSS has been described as inflammation of the muscles, tendons, and periosteum surrounding the tibia. Evidence of dysfunction and excessive tensile forces from the tibialis anterior, tibialis posterior, soleus, and flexor digitorum longus muscles acting on the tibia are commonly indicated as a cause for MTSS (Beck et al., 1994; Garth and Miller, 1989). Other evidence suggests that MTSS may also be caused by lower bone mineral density and repeated tibial bending (Beck, 1998; Magnusson et al., 2001; Moen et al., 2009).

Plantar Fasciitis

The plantar fascia is a thick connective tissue that spans the sole of the foot. The fascia can be divided into three bands: central, medial, and lateral. The central portion attaches at the medial tubercle of the calcaneus and divides into five segments near the head of each of the metatarsal bones. In comparison to the central band, the medial and lateral bands are considerably thinner. The medial band originates at the medial calcaneal tubercle and covers the adductor hallucis. The lateral band originates from the lateral tubercle and attaches to the base of the fifth metatarsal covering the abductor digiti minimi (Bartold, 2004). These three bands form the longitudinal arch which provides support to the foot and plays a critical role in maintaining the mechanical function of the foot during gait.

Plantar fasciitis typically presents as pain in the heel due to the plantar fascia becoming irritated, inflamed, or torn due to the repetitive stresses it undergoes in day-to-day life (Warren, 1990). Pain of the central band is often experienced at the attachment to the medial calcaneal tuberosity or 2-5cm beyond the calcaneus into the sole of the foot. Pain along the medial band is more likely to be experienced on the medial side of the calcaneus and along the arch of the foot. The least common type of pain occurs in the lateral band along the lateral portion of the calcaneus. Because pain caused by the medial and lateral bands does not fit the common description of plantar fasciitis, it may be misdiagnosed leading to unsuitable treatment and prolonged recovery.

While plantar fasciitis is one of the most common causes for heel pain, the causes of plantar fasciitis are often debated. Factors contributing to plantar fasciitis may include pes cavus or pes planus foot deformities, excessive foot pronation, overuse, and lower intrinsic foot muscle (IFM) volumes (Messier and Pittala, 1988; Cheung, 2015).

Achilles Tendinopathy

The Achilles tendon is formed by the merging of distal tendons from the gastrocnemius and soleus spanning approximately 15-26 cm before inserting on the posterior surface of the calcaneus. It is the largest and strongest tendon in the human body (Whiting & Zernicke, 2008). The Achilles tendon experiences loading up to 9 kN during running and 2.6 kN during walking (Komi et al., 1992). Tendinopathy to the mid-portion of the Achilles has been shown to be more common than damage at the insertional point (Knobloch et al., 2008). This is likely due to the zone of hypovascularity 2-7 cm proximal to the tendon insertion (Maffulli et al., 2004).

Lack of uniformity regarding the terms tendinopathy, tendinosis, and tendonitis has made the comparison of literature difficult. Tendinopathy refers specifically to the degenerative, noninflammatory condition affecting the Achilles tendon. Mechanisms involved in injuries to the Achilles tendon such as tendinopathies, tendinitis and rupture include excessive loading, anatomical malalignment, rapid dorsiflexion, and various intrinsic and extrinsic factors (Kader et al., 2002).

Stress Fractures and Fractures

Stress fractures and fractures of the tibia, fibula, metatarsals, navicular, and/or calcaneus are common in runners (McBryde, 1982). Stress fractures are primarily thought to be a response to chronic cyclical loading, while a full fracture might be caused by traumatic injury or the progression of a stress fracture that goes untreated. Repetitive summation of forces acting on the bone causes micro-damage within the bony matrix (Burr et al., 1985). Stress fractures occur when the accumulation of these forces and micro-damage exceed the stress bearing capacity of the bone and rate of bone repair (Stanitski et al., 1978; Burr et al., 1990). Pain caused by stress fractures usually develop gradually near the site and worsens with weight bearing activity.

Many etiological factors are believed to be associated with stress fractures. Higher initial loading rates, increased peak hip adduction, greater knee internal rotation, and greater rearfoot eversion were shown in athletes with a history of stress fractures and lower leg pain (Milner et al., 2006; Milner et al., 2005; Messier and Pittala, 1988). Intrinsic and extrinsic risk factors such as bone density, skeletal alignment, muscular strength, endurance, footwear, and training parameters may be key risk factors for developing stress fractures (Bennell, et al., 1999).

Intrinsic Factors Contributing to Running Related Injuries

Intrinsic factors predisposing runners to PFPS, ITBS, MTSS, Achilles tendinopathy, plantar fasciitis, and stress fracture/fracture can be divided into modifiable and non-modifiable categories. Modifiable factors include muscular deficits, kinematic patterns, and kinetic patterns. Non-modifiable risk factors include runner demographics such as age and biological sex, anatomical structure, and history of previous injury.

Male and female runners show similar overall injury rates with 20.4 and 20.8 injuries per 100 runners (Hollander et al., 2021). Some studies have reported female runners experiencing higher prevalence of injury in comparison to male runners, but Dempster et al. (2021) found these rates to not be statistically significant. However, biological sex has been suggested as a risk factor for specific injuries and injury risk associated with various running distances. Higher injury rates have been observed for men in distances exceeding 10 km, while women may experience higher injury rates in distances less than or equal to 10 km (Hollander et al., 2021). In the same meta-analysis, Hollander et al. (2021) reported that women were two times more likely to develop a bone stress injury (BSI) such as MTSS (Reinking et al., 2017) and stress fractures. This has been attributed to lower bone mineral density, kinematic patterns, calcium and vitamin D intake, and hormone balances (Lin et al., 2018).

Taunton et al. (2002) reported that females were twice as likely to develop ITBS and PFPS compared to men, mostly attributed to differences in biomechanical alignment. Conversely, men have been shown to be two to twelve times as likely to develop Achilles tendinopathies due to possible higher cumulated load and hormonal differences due to lower levels of estrogen (Hollander et al., 2021). Males have also been shown to have higher rates and risk of developing plantar fasciitis due to excessive loading or other variables that are not yet understood (Taunton et el., 2002; Sinclair et al., 2014). As the running population has shifted to include more female runners, it’s expected to see injuries that affect women at higher rates to show higher rates of overall prevalence.

Age is regarded as being a risk factor for developing running related injuries. As the average age of runners has increased, the greatest increases in distance running participation has been seen in the masters age group (≥ 50 years old). McKean et al. (2006) reported that masters runners were significantly more likely to be injured compared to younger runners and that they were more likely to suffer multiple injuries. Older runners are also more likely to have lower levels of flexibility, declines in muscular strength, and loss of bone density compared to their younger counterparts. Masters runners have been reported to experience higher initial vertical ground reaction force, higher vertical loading rate, lower peak vertical ground reaction force, greater knee flexion at foot contact, and less knee range of motion (Kline & Williams, 2015; Bus, 2003). Age has also been related to being susceptible to different types of running injuries. Both older and younger runners have the highest injury prevalence to the foot and knee. However, older runners have a higher prevalence of injuries to the Achilles and younger runners suffer more injuries to the knee and leg (McKean et al., 2006).

Muscular deficits have been found to play a role in running injuries. Runners with weak hip adductors have been shown to have significantly higher rates of ITBS and PFPS (Fredericson et al., 2000). Those with PFPS have also been shown to have significant muscular deficits compared to a control group in assessments of the knee stabilizing and hip extension muscles (Nunez et al., 2019). Women with PFPS showed less strength in both internal rotators of the hip and knee extensors (Oliveira et al., 2014). Similarly, runners with chronic plantar fasciitis have been shown to have lower rearfoot intrinsic foot volume compared to healthy runners (Cheung et al., 2015). Muscular deficits may also contribute to the development of stress fractures. Bennell et al. (2003) reported that greater muscle mass was a protective measure for stress fractures in runners.

Anatomical structure may play an important role in predisposing certain populations to higher rates of injury. One measurement in the frontal plane that is thought to have an effect on knee joint mechanics is the Q-angle. This angle is formed by the intersection of a line from the anterior superior iliac spine (ASIS) to the center of the patella and a second line from the anterior tibial tuberosity to the center of the patella. The Q-angle defines the frontal plane offset in resultant force vectors from the quadriceps and patellar tendons that create a lateral force on the patella (Powers, 2003). Males have an average Q-angle of 10-13 degrees, while females have an average Q-angle of 15-17 degrees. These gender differences put female runners at a greater risk to sustain an injury to the knee such as PFPS and ITBS compared to their male counterparts (Ferber et al., 2003). In addition, a 10% increase in Q-angle has been reported to increase stress on the PFJ by up to 45% (Huberti and Hayes, 1984).

Classifications of foot type based on anatomical alignment have been associated with greater incidence of lower extremity running injury. Those with high-arched and low-arched feet have been identified to be at greater risk, but the strength of these relationships is low (Tong & Kong, 2013). Evidence supports that injury patterns differ between different arch structures. High arched runners have been reported to have higher rates of ankle, bony and lateral injuries while low arched runners have higher rates of knee, soft tissue, and medial injuries (Williams et al., 2001a). Higher rates of injury may be due to increased rearfoot eversion, eversion to tibial internal rotation ratio, and rearfoot eversion velocity in low-arched runners; and increased vertical loading rate in high-arched runners (Williams et al., 2001b).

Pohl et al. (2009) and Riberio et al. (2011) studied runners currently experiencing plantar fasciitis or with a history of plantar fasciitis were compared with controls who had no history of plantar fasciitis. The studies found discrepancies in medial arch shape and runners experiencing plantar fasciitis. Pohl et al. (2009) reported higher incidence rates of plantar fasciitis in runners with lower medial longitudinal arches, while Riberio et al. (2011) reported elevated medial longitudinal arches in runners with symptoms and histories of plantar fasciitis. Results from these studies indicate that having either lower or higher longitudinal arches as opposed to an average arch height may put runners at higher risk of injuries.

Other anatomical differences associated with running injuries include excessive navicular drop, limb length discrepancy of more than 10 mm, and varus malalignments (Carvalho et al., 2011; van der Worp et al., 2015). Perhaps the highest intrinsic indicator for sustaining a running related injury is having sustained a previous injury. Runners with previous injury are up to nearly three times more likely to experience another injury (Macera et al., 1989). This is partially attributed to incomplete healing of the previous injury before returning to running. While these intrinsic variables may significantly factor into injury rates independently, the exact causes of running injuries are likely to range widely and consist of interactions between variables.

Kinematics of Running Related Injuries

Many studies have attempted to identify specific kinematic patterns that predispose runners to injuries. These kinematic patterns are commonly linked via the kinetic chain and are causative to a variety of injuries. However, results of these studies still remain inconsistent across the literature. Lack of confirmation across the literature suggests that specific kinematic patterns are not universal in causing running injuries, but may be more applicable to specific subpopulations.

Excessive rearfoot angles have been correlated to a variety of running injuries, although there is a lack of evidence linking rearfoot eversion with higher rates of plantar fasciitis. The studies by Pohl et al. (2009) and Riberio et al. (2011) reported no differences in rearfoot kinematics between groups with a history of plantar fasciitis and the control group. In both retrospective and prospective studies, increased eversion during running was a significant risk factor for the development of MTSS (Okunuki et al., 2019). This is thought to be due to increased activity of the soleus, flexor digitorim longus, and tibialis posterior generating strain on the posteromedial border of the tibia leading to inflammation. Similarly, Milgrom et al. (2007) found that excessive eversion leads to earlier fatigue of the tibialis posterior, increasing the medial tensile bone strain and the likelihood of tibial stress fractures. Since the tibialis posterior plays a primary role in in controlling rearfoot eversion, excessive eversion may result in earlier fatigue and greater tensile forces on the medial portion of the tibia, a common site for stress fractures (Pohl et al., 2008).

The mechanical coupling of the leg and foot suggests that tibial rotation can be linked to inversion and eversion of the foot. Hintermann et al. (1994) found that calcaneal eversion resulted in significant tibial internal rotation (TIR), but TIR did not directly result in calcaneal eversion. This coupling is frequently expressed as the eversion/tibial rotation ratio (EV/TIR) that occurs during stance. EV/TIR has been used to characterize runners into different injury patterns. Higher ratios with lower eversion are suggested to place runners at higher risk for foot injuries. Lower ratios resulting in greater transfer of transverse motion to the tibia are suggested to place runners at a higher risk for knee injury (Williams et al., 2001b).

Excessive rearfoot motion has been linked to knee injuries such as PFPS and ITBS, although the evidence is inconsistent. When examining EV/TIR ratio in runners, significant coupling differences were found in runners with anterior knee pain compared to those without pain (Rodriguez et al., 2014). However, two studies comparing rearfoot eversion in groups with and without PFPS found no differences between groups. Messier et al. (1991) found no significant differences in maximum rearfoot eversion, maximum eversion velocity, and total rearfoot movement. This led them to conclude that rearfoot movement was not a significant factor in the development of PFPS. Similarly, Powers et al. (2002) found no group differences in magnitude and timing of peak eversion and tibial rotation. They did however find differences within certain individuals. Results of studies focusing on PFPS indicate that a direct cause and effect relationship between rearfoot motion and the development of PFPS cannot be assumed. Still, some individuals with PFPS may experience excessive rearfoot motion, which could be a contributing factor to their symptoms.

Previous studies have also investigated potential relationships between rearfoot motion and the development of ITBS. It's expected that increased TIR would lead to increased ITB strain. Messier et al. (1995) found that individuals with ITBS had significantly higher maximum rearfoot inversion velocity, but no differences in maximum eversion and inversion compared to an uninjured control group. A meta-analysis performed by Mousavi et al. (2019) showed a decreased peak rearfoot eversion between male and female runners with ITBS compared to a control group. Other studies have reported no differences between rearfoot motion and the development of ITBS. Noehren et al. (2007) followed healthy runners over a two year period. Of the runners who developed ITBS, no significant rearfoot eversion differences were found.

ITBS and PFPS have been significantly linked to tibial rotation regardless of the existence of excessive rearfoot motion. Noehren et al. (2007) found that development of ITBS highly correlated to increased knee internal rotation. TIR increases the strain of the ITB causing greater compression of the LFE. In contrast, those with PFPS have also been demonstrated to have less knee internal rotation and greater tibial external rotation (Arazpour et al., 2016).

Achilles tendon injuries are also subject to the interaction between rearfoot motion and tibial rotation. At foot strike, the tibia is internally rotated due to eversion of the calcaneus and knee flexion. During mid-stance, the tibia is externally rotated due to extension of the knee. In the event of excessive eversion, rotation of the tibia will conflict at the proximal and distal ends. This leads to the “wringing out” of the Achilles tendon at the zone of hypo vascularity causing degenerative effects (Clement et al., 1984).

Knee movement in the sagittal plane also plays a role in the development of running injuries. Data suggest that lower knee flexion angles are associated with runners with PFPS and tibial stress fractures. Some have speculated that this is a compensatory response to reduce pain by decreasing the amount of contact pressure on the patella. Others believe this decreased knee flexion is a risk factor for PFPS (Boling et al., 2009). Milner et al. (2006) found that runners experiencing tibial stress fractures were more likely to have decreased knee flexion leading to increased stiffness of the lower extremity. The opposite can be said for the development of ITBS. Increased knee flexion angles allows the ITB to move into the impingement zone (Fairclough et al., 2006). Other studies have found no significant differences between knee flexion angles and runners developing ITBS (Noehren et al., 2007).

Further up the kinetic chain, various kinematic patterns of the hip joint such as hip adduction and internal rotation have been associated with running injuries. Hip adduction has been linked to both PFPS and ITBS, but conclusions throughout the literature are contradictory. Dierks et al. (2008) found that runners with PFPS displayed greater hip adduction due to muscular deficits of the hip abductor muscles. These results were similar to Wilson & Davis (2007), who reported that female runners with PFPS demonstrated greater hip adduction during running. Female runners are also thought to demonstrate higher levels of hip adduction compared to male runners as reported by Ferber et al. (2003). In contrast, Dierks et al. (2011) reported that runners with PFPS experienced less peak hip adduction during a prolonged run.

They hypothesized that this was due to runners attempting to reduce pain by decreasing the range of motion.

Similar trends in the literature can be found for the relationship between hip adduction and ITBS. Several studies have supported an increase in hip adduction during the stance phase for runners with ITBS compared to non-injured runners (Ferber et al., 2010; Noehren et al., (2007). Greater hip adduction stretches the ITB causing compression of the LFE. Still, many other studies examining hip kinematics in runners with ITBS show no change in hip adduction (Baker et al., 2010) or decreased hip adduction (Brown et al., 2016). Differences in study design including examining differences between sexes and measuring the effects of fatigue may be a factor in conflicting results.

Hip adduction has also been shown to be a factor in the development of tibial stress fractures. Pohl et al. (2008) found that peak hip adduction was greater in female runners who had previously experienced a tibial stress fracture. This was attributed to a lateral shift of the load placed on the knee resulting in compression of the lateral tibial condyle and increasing the tensile stress on the medial side of the bone.

Internal rotation of the femur is also associated with various running injuries including PFPS, ITBS, and MTSS. Following a systematic review, Meira et al. (2011) reported a correlation between hip internal rotation and PFPS. Internal rotation of the hip increases the Q angle, therefore increasing the contact pressure on the PFJ (Huberti & Hayes, 1984; Lee et al., 2003). Females on average run with greater hip internal rotation. However, both male and female runners with ITBS have demonstrated high levels of hip internal rotation (Ferber et al. 2003; Noehren et al., 2014).

Hip internal rotation has further been shown to be a factor in the development of MTSS in young female runners (Yagi et al., 2003). Runners with previous history of medial shin pain have higher peak hip internal rotation, though the differences from the control group is relatively small and may lack clinical significance (Loudon & Reiman, 2012).

Kinetics of Running Related Injuries

Numerous studies have attempted to understand the kinetic patterns that influence injury incidence in runners. Common kinetic variables explored related to running injuries include extension, abduction, tibial rotation, and inversion moments as well as ground reaction force (GRF) and contact forces. Sinclair and Self (2015) evaluated incidence of PFPS in female runners who are at a higher risk for developing the injury. Patellofemoral contacts force (PTF) was estimated as a function of knee flexion angle and knee extensor moment. Results of their study found that female runners exhibited significantly greater knee extension moments, knee abduction moments, and PTF than male runners. Discrepancies in results for runners with ITBS exist in the literature. Ferber et al. (2010) found significantly greater peak rearfoot invertor moment in female runners with a history of ITBS. However, Noehren et al. (2007) found no significant differences in kinetic patterns in runners with and without ITBS.

Runners with Achilles tendon pain have been shown to have reduced peak tibial external rotation moments. This is in contrast to traditional thought that those with Achilles tendinopathy have higher levels of torsional stress in the tendon (Munteanu & Christian, 2011). Bending forces about the anterior-posterior axis have been demonstrated to be a causative factor for tibial and other stress fractures (Milgrom et al., 1989). Given the similarities between stress fracture and MTSS etiology, this is likely a causative factor for the development of MTSS as well.

Whether or not a relationship between ground reaction forces and running related injuries such as PFPS and ITBS is often unclear in the literature, although significant results have been found. Esculier et al. (2015) found that decreased GRFs were dependent on foot strike pattern and were not universal in describing risk for PFPS. Significant group results for runners with

PFPS included maximum propulsion force, maximum braking force, and braking impulse (Messier et al., 1991). In a study analyzing GRFs in runners with and without ITBS, Messier et al. (1995) found significant differences only in maximum normalized braking force. Runners with ITBS running at a slightly higher speed than the control runners was a potentially confounding factor in this study. Grau et al. (2008) reported that runners with ITBS demonstrated greater lateral rearfoot impulse and lower medial forefoot force than in unmatched uninjured runners. The significance of these results were diminished once matching for gender, height, and weight occurred. Results of these studies show that ITBS may be more associated with kinematic alignment rather than kinetic variables.

Bony and soft tissue injuries such as MTSS, stress fractures, plantar fasciitis and Achilles tendinopathy have been associated with high impact loading. In studies comparing runners with Achilles tendinopathy to control participants, runners with Achilles tendinopathies experienced lower braking impulse and higher propulsion impulse (Baur et al., 2004). McCrory et al. (1999) found that runners with Achilles tendinitis did not have significant differences in vertical, anteroposterior, or mediolateral GRFs. Excessive and abnormal loading of the Achilles is a key predictor of overuse injury. A simple model of the Achilles tendon load (ATL) can be estimated as a function of the plantar flexion moment and the Achilles tendon moment arm as a function of the ankle sagittal plane angle (Self & Paine, 2001; Sinclair et al., 2014b). Excessive loading may lead to tendinopathy. Rice and Patel (2017) stated that it was unclear what levels of loading were harmful in vivo and whether magnitude or rate of loading were the most important factors in injury development.

Higher mechanical loading in runners with plantar fasciitis has been well documented throughout the literature. Runners with a history of plantar fasciitis have been found to have increased vertical loading rate, posterior and mediolateral vertical loading rates, and vertical stiffness at initial loading (Pohl et al., 2009; Johnson et al., 2020). Higher vertical loading rates leads to greater arch deformity increasing the strain of the plantar fascia. Results of these studies show high clinical significance and show a need for addressing impact loading to reduce the incidence of plantar fasciitis in runners.

Finally, runners with a history of tibial stress fractures have shown conflicting evidence for the role of GRF and the development of stress fracture. Primarily, studies have shown no significant relationship between GRFs and tibial stress fractures. Pohl et al. (2008), Bennell et al. (2004), and Zadpoor and Nikooyan (2010) found no significant difference in GRFs in runners with tibial stress fractures. Alternatively, Milner et al. (2006) reported that runners with a history of tibial stress fractures experienced significantly greater instantaneous and average loading rates during braking.

Extrinsic Risk Factors Contributing to Running Related Injuries

Extrinsic risk factors that have been significantly associated with running injuries include training errors, running shoes, and the type of running terrain/surface.

Training errors include factors such as neglecting a warmup, increasing mileage too quickly, consistently high weekly mileage, and lack of proper rest and recovery. The act of performing a proper warmup has long been advocated for in injury prevention programs. However, a warmup that relies on static stretching has been found to be ineffective at reducing injury risk. When the warmup focuses on increasing the body’s temperature, a significant reduction in injury risk has be found (Fradkin et al., 2006).

A common rule of thumb that runners may hear is the 10% rule. This rule means that runners should not increase their running mileage by more than 10% each week. In a study following 873 new runners, runners who increased their weekly mileage by more than 30% were more likely to sustain an injury compared to runners who followed the 10% rule. These runners were more likely to develop PFPS, ITBS, and MTSS. Plantar fasciitis, Achilles tendinopathy, and stress fractures were not linked to increased running distance in this study (Nielsen et al., 2014). Weekly mileage has been shown as a causative factor for running injury. van Gent et al. (2007) reported that running more than 40 miles per week in men was associated with higher risk of sustaining an injury. Similarly, as frequency of running increased, so did injury rates (Jacobs & Berson, 1986). Many of these studies neglected to control for weekly mileage.

A specific concern within the injury statistics from 1971-1979 was the nearly doubled incidence rate of knee injuries over a ten year period. While it's widely hypothesized that poor skeletal alignment and high mileage played a role in this spike in knee injuries, advancements in the shoe industry may have inadvertently had a negative effect. The addition of a heel wedge that provided cushioning material and alleviated injuries to the Achilles tendon and heel may have left runners with poor rearfoot control causing excessive eversion (Cavanagh, 1980 & Larson and Katovsky, 2012). Research on whether or not shoes should be assigned based on foot type or kinematic and kinetic patterns are generally inconclusive and contradictory. A concern for footwear is the degenerative quality after repeated use. Wang et al. (2010) reported a nearly 5% increase in peak force after 500km of use.

Various terrains and running surfaces are often used by runners for training and competition. Downhill running increases the amount of stress placed on the knees leading to injuries like PFPS and ITBS, while uphill running increases the stress on the Achilles and calf leading to Achilles tendinopathy. Mechanical differences have also been observed over asphalt, acrylic, and rubber modified surfaces. Dixon et al. (2000) observed differences in peak loading rate across the three surfaces, although group kinematic differences were not significant in this study. Rather, it was reported that while some runners demonstrated sagittal plane kinematic changes, the mechanisms for adaptations to various surfaces requires a more individual analysis.

The exact causes of running injuries are likely to be diverse and consist of a variety of interactions between intrinsic and extrinsic risk factors. It’s likely that the exact mechanism for injury requires a much more individualized approach than exists in current literature.

Insoles and Orthotics

Insoles and orthotics have grown to be popular solutions for many foot, knee, and back pathologies to reduce the frequency of movement related injuries, align the skeleton, improve impact cushioning, improve sensory feedback, and/or improve comfort (Nigg et al., 1999). In 2021, the global foot orthotic and insole market was valued at 3.49 billion dollars. The market is projected to grow to 3.93 billion in 2022 and to 6.15 billion by 2029, a 6.6% compound annual growth rate. The market can be segmented into medical, sport and athletics, and personal uses. While the medical segment holds the largest share, the sport and athletics segment is the second largest and expected to grow (Fortune Business Insights, 2022).

The terms insoles and orthotics are often used interchangeably, but the products differ. Both products function by offering cushion and support to the foot. However, the American College of Foot and Ankle Orthopedic Medicine defines a “true orthosis” or a prescription custom foot orthosis (PCFO) as being “created specifically to address the pathomechanical features of a foot condition that may be structural or functional in nature (ACFAOM, 2006).” PCFOs are made from the mold of the foot while the subtalar joint is in the neutral position, allowing the device to maintain the subtalar and midtarsal joints in the corrected positions when worn (Davidson, 2017). PCFOs have an estimated lifetime of five years, while prefabricated insoles have an estimated lifespan of six months to a year.

Prefabricated or over-the-counter insoles are mass produced and designed to fit a range of individuals and can be categorized as functional or accommodative. Accommodative insoles are made to provide relief or protection to the foot, but typically don’t address functional needs.

Accommodative insoles are commonly referred to as flexible insoles, which are often made from gel or foam that function to relieve pressure on the foot, provide cushion, and act as shock absorbers. Functional insoles include rigid and semi-rigid insoles which primarily act to control foot and gait biomechanics. Rigid insoles are generally made from plastic and carbon fiber and have the sole function of restricting and controlling abnormal foot movement and correcting malalignment. Semi-rigid insoles are generally made of soft materials reinforced by a rigid shell and serve to combine the cushioning benefits of a flexible insole with the motion control of rigid insoles (Zaloha et al., 2021). Many athletes attempt to self-treat an injury with these, and it's not uncommon for medical professionals to suggest prefabricated insoles before referring patients to a podiatric specialist (Davidson, 2017).

One obstacle to the use of orthotics over prefabricated inserts is cost. Ring and Otter (2014) found that over-the-counter insoles cost 38% less when compared to the average cost of casted orthotics. Along with more appealing costs to consumers, proof of efficacy of PCFO's over prefabricated insoles remains inconsistent in research. Many studies have shown that there is not a significant difference between prefabricated insoles and custom orthotics when treating and preventing foot and lower extremity injuries.

Ring and Otter (2014) followed 67 patients with plantar heel pain who received either casted foot orthoses or prefabricated semi-rigid insoles. After eight weeks both groups had significantly reduced foot pain, and there was no significant difference between groups. Similarly, Baldassin et al. (1986) followed 125 participants with plantar fasciitis who received either custom foot orthotics or prefabricated insoles both made from ethylene vinyl acetate (EVA). After eight weeks both groups had significantly reduced foot pain, and there was no significant difference between groups. In a study examining kinematic parameters, 24 recreational runners ran for twenty minutes at 80% of their maximal aerobic speed with custom made orthotics, prefabricated insoles, and a control condition. No significant differences between conditions on knee flexion and foot eversion were found (Gil-Calvo et al., 2020).

Plantar loading parameters during running have been examined to compare prefabricated insoles and custom orthotics. Lucas-Cuevas et al. (2014a) studied runners using custom orthotics, prefabricated insoles, and the original insoles of their running shoes. Both custom orthotics and prefabricated insoles reduced loading of the foot compared to the control. Custom orthotics were found to have less plantar loading of the heel compared to the prefabricated insole. Finally, prefabricated insoles have also been shown to be more than or equally as comfortable as custom orthotics. Lucas-Cuevas et al. (2014b) reported that both custom made orthotics and prefabricated insoles were perceived as being significantly more comfortable than original shoe insoles. They noted that these differences were clinically significant and may be cause for modifications in running gait. In fact, they reported that prefabricated insoles were perceived as being more comfortable than custom orthotics, though not statistically significant. By performing to at least equal standards as custom orthotics both biomechanically and in perceived comfort, prefabricated insoles stand as a reasonable alternative.

Kinematic Changes with Prefabricated Insoles

The use of prefabricated insoles serves to manipulate the kinematics of the foot, which is expected to result in changes in the knee and hip as part of a closed kinematic chain. As previously stated, the mechanical coupling of the leg and foot shows a direct relationship between eversion of the subtalar joint and tibial rotation.

The most commonly reported kinematic adjustment is rearfoot eversion. In studies examining the effects of prefabricated insoles, there have been significant results for reduction in eversion and inversion-eversion range of motion. Smith et al. (1986) compared runners using semi-rigid and soft insoles and found that semi-rigid insoles provided significant reductions in peak eversion and eversion velocity. Similar results have been found with rigid insoles (Novick and Kelley, 1990). The use of insoles has been shown to have effects in both walking and running. Majumdar et al. (2013) found significant reductions of 3.8 and 2.5 degrees in rearfoot eversion in walking and running, respectively. Studies have also found no significant differences in rearfoot eversion (Gil-Calvo et al., 2020; Nawoczenski et al., 1995, Dixon, 2007) or even increased ankle eversion when using prefabricated insoles (Donoghue et al., 2008). Observed changes in rearfoot eversion are often small, but may have cumulative effects for runners.

Increased eversion during running is associated with the development of MTSS and subsequent stress fractures. Thus, the use of prefabricated insoles to reduce eversion of the foot may decrease the incidence of MTSS and stress fractures. In runners with PFPS, Eng and Pierrynowski (1994) found that significant frontal and transverse plane motion of the subtalar joint and knee existed with the use of insoles. Sutlive et al. (2004) also reported that patients with PFPS and forefoot valgus alignment or a navicular drop of 3mm respond well to intervention with a prefabricated insole. Both of these studies also show a potential interaction between physiotherapy or activity modification and prefabricated insoles on PFPS. Similar frontal and transverse plane differences were found in a study involving runners with plantar fasciitis. Though there were no differences in plantar fascia strain, rearfoot range of motion was significantly reduced with the use of insoles compared to the without insole condition (Sinclair et al., 2015b).

Studies have found significant differences in the coupling mechanism between calcaneal inversion and eversion with tibial rotation when using insoles. Mündermann et al. (2003) found significant differences in rearfoot eversion and decreased tibial internal rotation with a medial post insole. While some studies have not corroborated the findings of decreased ankle eversion with insole use, differences in tibial internal rotation as part of the kinetic chain have still been observed. Stacoff et al. (2008) and Nawoczenski et al. (1995) found no significant differences in ankle eversion, but found significant changes in tibial rotation when using insoles. Both studies showed a decrease in internal tibial rotation with insoles, with Nawoczenski et al. (1995) finding a significant effect on the coupling relationship between calcaneal eversion and tibial rotation.

Researchers have shown that hip internal rotation and adduction may be influenced by the use of prefabricated insoles. Braga et al. (2019) found that medially wedged insoles reduced the amount of hip range of motion in the transverse and frontal planes. Decreased in movement in these planes put runners at less risk for developing injuries such as ITBS, PFPS, MTSS, and tibial stress fractures.

Kinetic Changes with Prefabricated Insoles

The primary variables used to evaluated kinetic effects of insoles include loading rates and peak ground reaction forces. However, results of these studies vary across the literature. Dixon (2007) found no difference in peak eversion angle but observed key differences in peak impact force, average loading rate, a peak rate of loading when using commercially available insoles while running in military boots. However, Mündermann et al., (2003) found that medial post insoles increased the vertical loading rate.

Sinclair et al., (2016) also examined the effects of insoles on the PFJ. A significant main effect was found for peak patellofemoral force. Furthermore, peak patellofemoral force was significantly greater in both insole conditions compared to the no insole condition. A significant main effect was also found for patellofemoral impulse. Once again, patellofemoral impulse was greater in both insole conditions compared to the no insole condition. Based on results of this study, the use of insoles could be detrimental to the development of anterior knee pain in female runners.

Sinclair et al., (2016) sought to observe variability in Achilles tendon kinetics between prefabricated insoles, semi-custom, and no insole conditions. No significant differences were found in peak Achilles tendon force, average loading rate, or impulse. While there was no reduction in Achilles loading, the use of insoles did not put runners at any greater risk for developing Achilles pathologies. These results were congruent with results from Sinclair et al., (2014b) who found that orthotics reduced the load of the Achilles tendon in runners.

Taunton et al. (2002) reported that nearly 50% of patients with plantar fasciitis were recommended to use insoles or orthotics. Due to the high correlation of impact forces on the development of plantar fasciitis and moderate evidence of insoles decreasing the loading rates of the foot, prefabricated insoles may be useful tools for the treatment or prevention of plantar fasciitis. In a study examining short and long term effects of insoles and orthotics on symptoms of plantar fasciitis, improvements were found when using prefabricated insoles for short term benefits. No significant long term effect was found compared to the control (Landorf et al., 2006).

Other observed kinetic changes with the use of insoles include ankle inversion moment and knee external rotation moment. Mündermann et al. (2003) found that medially posted insoles reduced ankle inversion and maximum knee external rotation moments in runners. Rsults of reported reductions in ankle inversion angle are congruent with results found Nigg et al. (2003). Alternatively, Nigg et al. (2003) reported that maximum knee external rotation moment was 27.6% higher for the full medial insole condition compared to a neutral insole. A smaller inversion moment may suggest that less strain on the ankle invertor muscles such as the tibialis posterior which act eccentrically to control eversion (MacLean et al., 2013).

Perception of Comfort

Perceived comfort of footwear has been hypothesized as a protective measure for running related injuries. For example, perceptions of discomfort may lead to alterations in muscular activity of the leg, increasing the risk for injury and decreasing running economy (Mündermann et al., 2001; Luo et al., 2009). Comfort is not easily defined as it is a subjective measurement to every individual. However, comfort also seems to play a key role in the selection and benefit of insole usage. Based on the lack of conclusive evidence for biomechanical injury predictors, Nigg et al. (2015) suggested two new paradigms for running injury prevention: ‘preferred movement path’ and ‘comfort filter’. These paradigms assume that a person will instinctively choose a more comfortable footwear option using their comfort filter, which will allow them to move within their preferred movement path.

Studies based on comfort have found significant decreases in frequency of injury for insole conditions which participants found more comfortable (Mündermann et al., 2001). Similarly, conditions that are more comfortable show a significant improvement of .7% for running economy (Luo et al., 2009). One caveat to the comfort filter is that people within different functional groups may require different functional features of an insole. Thus, studies that do not provide multiple insole options for various structural features may not meet the comfort needs of their participants.

One study showed that participants found greater comfort in products with a dynamicflexible construction, such as Currex, over a more rigid insole, such as PowerStep (Braunstein et al., 2015). This study was in line with the previous findings that softer insoles are perceived to be more comfortable than hard insoles (Mündermann et al., 2002). In a systematic review, Richter et al. (2011) found that adverse effects of foot orthoses were reported in 8 of the 23 observed studies. These studies included a mix of PCFOs and prefabricated insoles. The most commonly reported adverse effect reported was discomfort, which was attributed as the main reason for discontinuing the use of orthotics or insoles. While perceptions of comfort are one of the more subjective measurements in biomechanical research, evaluation and methods to quantify it may play an important role in future research.

Plantar Pressure

Many studies have attempted to relate comfort of insoles to plantar pressure distribution of the foot. However, the relationship remains unclear. Chen et al. (1994) reported that increased plantar pressure at the midfoot, providing a more even pressure distribution, was more comfortable than increased pressure at the forefoot and hallux. Similarly, Wegener et al. (2008) found correlations between reduced peak pressure and comfort when comparing neutral cushioned running shoes to a control. Alternatively, Jordan and Bartlett (1995) found that significant differences in perceived comfort were not supported by significant changes in pressure distribution patterns. Braunstein et al. (2015) also did not find any significant correlation between plantar pressure pattern and perceived comfort. The authors proposed that while plantar pressure may still be an influential variable, runners prioritize factors such as hardness and flexibility in their comfort ratings.

Sneyers et al. (1995) studied the effect of foot type on plantar loading and showed a difference in plantar pressures based on pes planus, pes cavus, and neutral arch foot types. Their results showed that pes cavus foot types had plantar heel loads directed towards the anterior calcaneus, lower loads in the midfoot, and higher loads in the forefoot compared to pes planus. These findings support the use of inserts in high arched individuals to produce a shift of the load in the foot, thus making the shoe more comfortable. There is likely still more to be understood on the influence of plantar pressure as an evaluation tool for comfort, performance, and injury prevention.

References

ACFAOM. (2006). The American college of foots & ankle orthopedics & medicine. Prescription custom foot orthoses practice guidelines.

Almeida, G. P. L., Silva, A. P. de M. C. C. e, França, F. J. R., Magalhães, M. O., Burke, T. N., & Marques, A. P. (2016). Q-angle in patellofemoral pain: Relationship with dynamic knee valgus, hip abductor torque, pain and function. *Revista Brasileira de Ortopedia, 51*(2), 181–186.

Andersen, J. J. (2021, September 21). *The state of running 2019*. Athletic shoe reviews. Retrieved April 2022, from https://runrepeat.com/state-of-running

Arazpour, M., Bahramian, F., Abutorabi, A., Nourbakhsh, S. T., Alidousti, A., & Aslani, H. (2016). The effect of patellofemoral pain syndrome on gait parameters: A literature review. *Archives of Bone and Joint Surgery, 4*(4), 298–306.

Baldassin, V., Gomes, C. R., & Beraldo, P. S. (2009). Effectiveness of prefabricated and customized foot orthoses made from low-cost foam for noncomplicated plantar fasciitis: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*, *90*(4), 701–706.

Baker, R. L., Souza, R. B., Rauh, M. J., Fredericson, M., & Rosenthal, M. D. (2018). Differences in knee and hip adduction and hip muscle activation in runners with and without iliotibial band syndrome. *PM & R: The Journal of Injury, Function, and Rehabilitation, 10(*10), 1032–1039.

Bartold, S. J. (2004). The plantar fascia as a source of pain—Biomechanics, presentation and treatment. *Journal of Bodywork and Movement Therapies*, *8*, 214–226.

Batt, M.E. (1995). Shin splints-a review of terminology. *Clinical Journal of Sports Medicine* 5:53-57.

Baur, H., Divert, C., Hirschmüller, A., Müller, S., Belli, A., & Mayer, F. (2004). Analysis of gait differences in healthy runners and runners with chronic Achilles tendon complaints. *Isokinetics and Exercise Science, 12*(2), 111–116.

Beck, R., T, M. S., Osternig, L. R., & Oregon, P. D. T. E. (1994). Medial tibial stress syndrome—The location of muscles in the leg in relation to symptoms. *Journal of Bone and Joint Surgery*, 1057–1061.

Bennell, K. L., Malcolm, S. A., Thomas, S. A., Reid, S. J., Brukner, P. D., Ebeling, P. R., & Wark, J. D. (1996). Risk factors for stress fractures in track and field athletes. A twelve month prospective study. *The American Journal of Sports Medicine, 24*(6), 810–818.

Bennell, K., Crossley, K., Jayarajan, J., Walton, E., Warden, S., Kiss, Z. S., & Wrigley, T. (2004). Ground reaction forces and bone parameters in females with tibial stress fracture. *Medicine & Science in Sports & Exercise, 36*(3), 397–404.

Beverly, J. (2016). 50 years of (mostly) fantastic footwear innovation. *Runner's World*.

Boling, M. C., Padua, D. A., Marshall, S. W., Guskiewicz, K., Pyne, S., & Beutler, A. (2009). A prospective investigation of biomechanical risk factors for patellofemoral pain syndrome. The joint undertaking to monitor and prevent ACL injury (JUMP-ACL) cohort. The *American Journal of Sports Medicine, 37*(11), 2108–2116.

Braga, U. M., Mendonça, L. D., Mascarenhas, R. O., Alves, C. O. A., Filho, R. G. T., & Resende, R. A. (2019). Effects of medially wedged insoles on the biomechanics of the lower limbs of runners with excessive foot pronation and foot varus alignment. *Gait & Posture, 74*, 242–249.

Braunstein, B., Schulze, N., Sanno, M., & Bruggemann, G.-P. (2015). Comfort and plantar pressure pattern during running with prefabricated insoles. *33rd International Conference on Biomechanics in Sports*, 536–539.

Burr, D.B., Martin, R.B., Shaffler, M.B., Radin, E.L., 1985. Bone remodeling in response to in vivo fatigue microdamage. *Journal of Biomechanics, 18*, 189–200.

Burr, D.B., Milgrom, C., Boyd, R.D., Higgins, W.L., Robin, G., Radin, E.L., 1990. Experimental stress fracture of the tibia. *The Journal of Bone and Joint Surgery, 72-B*, 370–375.

Bus SA. (2003). Ground reaction forces and kinematics in distance running in older-aged men. *Medicine and Science in Sports Exercise, 35*(7), 1167-1175

Cavanagh, P. R. (1980) *The Running Shoe Book.* Anderson World.

Chen, H., Nigg, B. M., & de Koning, J. (1994). Relationship between plantar pressure distribution under the foot and insole comfort. *Clinical Biomechanics (Bristol, Avon), 9*(6), 335–341.

Clement, D. B., Taunton, J. E., & Smart, G. W. (1984). Achilles tendinitis and peritendinitis: Etiology and treatment. The American Journal of Sports Medicine, 12(3), 179–184.

Cooper K.H. (1968). *Aerobics*. New York, NY: Bantam Books/Random House Publishing.

Davidson, D. M. (2017). Prefabricated insoles and modifications. In M. B. Werd, E. L. Knight, & P. R. Langer (Eds.), *Athletic Footwear and Orthoses in Sports Medicine*, 115–120.

Dempster, J., Dutheil, F., & Ugbolue, U. C. (2021). The prevalence of lower extremity injuries in running and associated risk factors: A systematic review. *Physical Activity and Health, 5*(1), 133–145.

Dierks, T. A., Manal, K. T., Hamill, J., & Davis, I. S. (2008). Proximal and distal influences on hip and knee kinematics in runners with patellofemoral pain during a prolonged run. *The Journal of Orthopaedic and Sports Physical Therapy, 38*(8), 448–456.

Dierks, T. A., Manal, K. T., Hamill, J., & Davis, I. (2011). Lower extremity kinematics in runners with patellofemoral pain during a prolonged run. *Medicine and Science in Sports and Exercise, 43*(4), 693–700.

Dixon, S. J. (2007). Influence of a commercially available orthotic device on rearfoot eversion and vertical ground reaction force when running in military footwear. *Military Medicine, 172*(4), 446–450.

Dixon, S. J., Collop, A. C., & Batt, M. E. (2000). Surface effects on ground reaction forces and lower extremity kinematics in running. *Medicine & Science in Sports & Exercise*, *32*(11), 1919–1926. https://doi.org/10.1097/00005768-200011000-00016

Donoghue, O. A., Harrison, A. J., Laxton, P., & Jones, R. K. (2008). Orthotic control of rear foot and lower limb motion during running in participants with chronic Achilles tendon injury. *Sports Biomechanics*, *7*(2), 194–205.

Eng, J. J., & Pierrynowski, M. R. (1994). The effect of soft foot orthotics on three-dimensional lower-limb kinematics during walking and running. *Physical Therapy, 74*(9), 836–844.

Esculier, J.-F., Roy, J.-S., & Bouyer, L. J. (2015). Lower limb control and strength in runners with and without patellofemoral pain syndrome. *Gait & Posture*, *41*(3), 813–819.

Ferber, R., Noehren, B., Hamill, J., & Davis, I. (2010). Competitive female runners with a history of iliotibial band syndrome demonstrate atypical hip and knee kinematics. *Journal of Orthopaedic & Sports Physical Therapy, 40*(2), 52–58.

Ferber, R., McClay Davis, I., & Williams III, D. S. (2003). Gender differences in lower extremity mechanics during running. *Clinical Biomechanics*, *18*(4), 350–357.

Foot Orthotic Insoles Market Size, Share | Growth Analysis, 2029. Fortune Business Insights. (n.d.). Retrieved April, 2022, from https://www.fortunebusinessinsights.com/industryreports/foot-orthotic-insoles-market-100348

Gil-Calvo, M., Jimenez-Perez, I., Priego-Quesada, J. I., Lucas-Cuevas, Á. G., & Pérez-Soriano, P. (2020). Effect of custom-made and prefabricated foot orthoses on kinematic parameters during an intense prolonged run. *PLOS ONE*, *15*(3), e0230877

Grau, S., Maiwald, C., Krauss, I., Axmann, D., & Horstmann, T. (2008). The influence of matching populations on kinematic and kinetic variables in runners with iliotibial band syndrome. *Research Quarterly for Exercise and Sport, 79*(4), 450–457.

Haberman, A. (2017). Escape and pursuit: contrasting visions of the 1970s long-distance running boom in American popular culture. *Sport History Review, 48*(1), 1–17.

Hamill, J., & Knutzen, K. (2003). *Biomechanical basis of human movement*. Philadelphia: Lippincott Williams & Wilkins.

Hamill, J., Miller, R., Noehren, B., Davis, I. (2008). A prospective study of iliotibial band strain in runners. *Clinical Biomechanics. 23*: 1018-1025.

Fairclough, J., Hayashi, K., Toumi, H., Lyons, K., Bydder, G., Phillips, N., Best, T. M., & Benjamin, M. (2006). The functional anatomy of the iliotibial band during flexion and extension of the knee: Implications for understanding iliotibial band syndrome. *Journal of Anatomy, 208*(3), 309–316.

Fairclough, J., Hayashi, K., Toumi, H., Lyons, K., Bydder, G., Phillips, N., Best, T. M., & Benjamin, M. (2007). Is iliotibial band syndrome really a friction syndrome? *Journal of Science and Medicine in Sport, 10*(2), 74–76.

Ferber, R., Davis, I. M., & Williams, D. S. (2003). Gender differences in lower extremity mechanics during running. *Clinical Biomechanics (Bristol, Avon), 18*(4), 350–357.

Ferber, R., Noehren, B., Hamill, J., & Davis, I. S. (2010). Competitive female runners with a history of iliotibial band syndrome demonstrate atypical hip and knee kinematics. *The Journal of Orthopaedic and Sports Physical Therapy, 40*(2), 52–58.

Fields, K. B. (2011). Running injuries - Changing trends and demographics. *Current Sports Medicine Reports, 10*(5), 299-303.

Fokkema T, Hartgens F, Kluitenberg B, et al. (2019). Reasons and predictors of discontinuation of running after a running program for novice runners. *J Sci Med Sport. 22*(1),106-111.

Fradkin, A. J., Gabbe, B. J., & Cameron, P. A. (2006). Does warming up prevent injury in sport?: The evidence from randomized controlled trials? *Journal of Science and Medicine in Sport, 9*(3), 214–220.

Fredericson,M. Cookingham, C.L, Chaudhari, A.M., Dowdell, B.C., Oestreicher, N., Sahrmann, S.A. (2000). Hip abductor weakness in distance runners wit iliotibial band syndrome. *Clinical Journal Sports Medicine. 10*: 169-175.

Garth, W. P., & Miller, S. T. (1989). Evaluation of claw toe deformity, weakness of the foot intrinsics, and posteromedial Shin Pain. *The American Journal of Sports Medicine, 17*(6), 821–827.

Gil-Calvo, M., Jimenez-Perez, I., Priego-Quesada, J. I., Lucas-Cuevas, Á. G., & Pérez-Soriano, P. (2020). Effect of custom-made and prefabricated foot orthoses on kinematic parameters during an intense prolonged run. *PLOS ONE, 15*(3), e0230877.

Hollander, K., Rahlf, A. L., Wilke, J., Edler, C., Steib, S., Junge, A., & Zech, A. (2021). Sex specific differences in running injuries: A systematic review with meta-analysis and meta-regression. *Sports Medicine (Auckland, N.z.), 51*(5), 1011–1039.

Huberti, H. H., & Hayes, W. C. (1984). Patellofemoral contact pressures. The influence of q angle and tendofemoral contact. *The Journal of Bone and Joint Surgery, 66*(5), 715–724.

Johnson, C. D., Tenforde, A. S., Outerleys, J., Reilly, J., & Davis, I. S. (2020). Impact-related ground reaction forces are more strongly associated with some running injuries than others. *The American Journal of Sports Medicine, 48*(12), 3072–3080.

Jordan, C., & Bartlett, R. (1995). Pressure distribution and perceived comfort in casual footwear. *Gait & Posture*, *3*(4), 215–220.

Kakouris, N., Yener, N., & Fong, D. T. P. (2021). A systematic review of running-related musculoskeletal injuries in runners. *Journal of Sport and Health Science, 10*, 513-522.

Kline, P. W., & Williams, D. S. B. (2015). Effects of normal aging on lower extremity loading and coordination during running in males and females. *International Journal of Sports Physical Therapy, 10*(6), 901–909.

Knobloch, K., Yoon, U., & Vogt, P. M. (2008). Acute and overuse injuries correlated to hours of training in master running athletes. *Foot & Ankle International*, *29*(7), 671–676.

Landorf, K. B., Keenan, A.-M., & Herbert, R. D. (2006). Effectiveness of foot orthoses to treat plantar fasciitis: A randomized trial. *Archives of Internal Medicine*, *166*(12), 1305–1310.

Larson, P., & Katovsky, B. (2012). *Tread lightly: form, footwear, and the quest for injury free running.* Skyhorse Pub.

Lee, T. Q., Morris, G., & Csintalan, R. P. (2003). The influence of tibial and femoral rotation on patellofemoral contact area and pressure. *The Journal of Orthopaedic and Sports Physical Therapy, 33*(11), 686–693.

Lee, D.-chul, Brellenthin, A. G., Thompson, P. D., Sui, X., Lee, I.-M., & Lavie, C. J. (2017). Running as a key lifestyle medicine for longevity. *Progress in Cardiovascular Diseases, 60*(1), 45–55.

Lin, C., Casey, E., Herman, D., Katz, N., & Tenforde, A. (2018). Sex differences in common sports injuries. PM & R : *The Journal of Injury, Function, and Rehabilitation, 10*(10), 1073–1082.

Loudon, J. K. (2016). Biomechanics and pathomechanics of the patellofemoral joint. *International Journal of Sports Physical Therapy, 11*(6), 820–830.

Lucas-Cuevas, A. G., Pérez-Soriano, P., Llana-Belloch, S., Macián-Romero, C., & Sánchez Zuriaga, D. (2014a). Effect of custom-made and prefabricated insoles on plantar loading parameters during running with and without fatigue. *Journal of Sports Sciences, 32*(18), 1712–1721.

Lucas-Cuevas, A. G., Pérez-Soriano, P., Priego-Quesada, J. I., & Llana-Belloch, S. (2014b). Influence of foot orthosis customisation on perceived comfort during running. *Ergonomics, 57*(10), 1590–1596.

Luo, G., Stergiou, P., Worobets, J., Nigg, B., & Stefanyshyn, D. (2009). Improved footwear comfort reduces oxygen consumption during running. *Footwear Science, 1*(1), 25–29.

Macera, C. A., Pate, R. R., Powell, K. E., Jackson, K. L., Kendrick, J. S., & Craven, T. E. (1989). Predicting lower-extremity injuries among habitual runners. *Archives of Internal Medicine, 149*(11), 2565–2568.

MacLean, C. L., Davis, I. S., & Hamill, J. (2008). Short- and long-term influences of a custom foot orthotic intervention on lower extremity dynamics. *Clinical Journal of Sport Medicine: Official Journal of the Canadian Academy of Sport Medicine, 18*(4), 338–343.

Magnusson, H.I., Westlin, N.E., Nyqvist, F., Gardsell, P., Seeman, E, & Karlsson, M.K. (2001). Abnormally decreased bone regional density in athletes with medial tibial stress syndrome. *American Journal of Sports Medicine, 29*. 712-715.

Majumdar, R., Laxton, P., Thuesen, A., Richards, B., Liu, A., Arán-Ais, F., Parreño, E. M., & Nester, C. J. (2013). Development and evaluation of prefabricated antipronation foot orthosis. *Journal of Rehabilitation Research and Development, 50*(10), 1331–1342.

McBryde, A. M. (1982). Stress fractures in runners. *Sports Medicine*, 5(7), 914–928.

McCrory, J. L., Martin, D. F., Lowery, R. B., Cannon, D. W., Curl, W. W., Read, H. M. J., Hunter, D. M., Craven, T., & Messier, S. P. (1999). Etiologic factors associated with Achilles tendinitis in runners. *Medicine & Science in Sports & Exercise*, *31*(10), 1374-1381.

McKean, K. A., Manson, N. A., & Stanish, W. D. (2006). Musculoskeletal injury in the masters runners. *Clinical Journal of Sport Medicine, 16*(2), 149–154.

Messier, S. P., Edwards, D. G., Martin, D. F., Lowery, R. B., Cannon, D. W., James, M. K., Curl, W. W., Read, H. M., & Hunter, D. M. (1995). Etiology of iliotibial band friction syndrome in distance runners. *Medicine and Science in Sports and Exercise, 27*(7), 951–960.

Messier, S. P., Davis, S. E., Curl, W. W., Lowery, R. B., & Pack, R. J. (1991). Etiologic factors associated with patellofemoral pain in runners. *Medicine and Science in Sports and Exercise*, *23*(9), 1008–1015.

Messier, S. P., & Pittala, K. A. (1988). Etiologic factors associated with selected running injuries. *Medicine and Science in Sports and Exercise, 20*(5), 501–505.

Milgrom, C., Giladi, M., Simkin, A., Rand, N., Kedem, R., Kashtan, H., Stein, M., & Gomori, M. (1989). The area moment of inertia of the tibia: A risk factor for stress fractures. *Journal of Biomechanics*, *22*(11–12), 1243–1248.

Milgrom, C., Radeva-Petrova, D. R., Finestone, A., Nyska, M., Mendelson, S., Benjuya, N., Simkin, A., & Burr, D. (2007). The effect of muscle fatigue on in vivo tibial strains. *Journal of Biomechanics*, *40*(4), 845–850.

Milner, C. E., Ferber, R., Pollard, C. D., Hamill, J., & Davis, I. S. (2006). Biomechanical factors associated with tibial stress fracture in female runners. *Medicine and Science in Sports and Exercise, 38*(2), 323–328.

Milner, C. E., Hamill, J., & Davis, I. S. (2010). Distinct hip and rearfoot kinematics in female runners with a history of tibial stress fracture. *Journal of Orthopaedic & Sports Physical Therapy*, *40*(2), 59–66.

Moen, M. H., Tol, J. L., Weir, A., Steunebrink, M., & De Winter, T. C. (2009). Medial tibial stress syndrome: a critical review. *Sports Medicine, 39*(7), 523–546.

Mousavi, S. H., Hijmans, J. M., Rajabi, R., Diercks, R., Zwerver, J., & van der Worp, H. (2019). Kinematic risk factors for lower limb tendinopathy in distance runners: A systematic review and meta-analysis. *Gait & Posture*, *69*, 13–24.

Mündermann, A., Stefanyshyn, D. J., & Nigg, B. M. (2001). Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Medicine & Science in Sports & Exercise*, *33*(11), 1939–1945.

Mündermann, A., Nigg, B. M., Stefanyshyn, D. J., & Humble, R. N. (2002). Development of a reliable method to assess footwear comfort during running. *Gait & Posture*, *16*(1), 38–45.

Mündermann, A., Nigg, B. M., Humble, R. N., & Stefanyshyn, D. J. (2003). Foot orthotics affect lower extremity kinematics and kinetics during running. Clinical Biomechanics (Bristol, Avon), 18(3), 254–262.

Nawoczenski, D. A., Cook, T. M., & Saltzman, C. L. (1995). The effect of foot orthotics on three-dimensional kinematics of the leg and rearfoot during running. The Journal of Orthopaedic and Sports Physical Therapy, 21(6), 317–327.

Nielsen, R. Ø., Parner, E. T., Nohr, E. A., Sørensen, H., Lind, M., & Rasmussen, S. (2014). Excessive progression in weekly running distance and risk of running-related injuries: An association which varies according to type of injury. *The Journal of Orthopaedic and Sports Physical Therapy*, *44*(10), 739–747.

Nigg, B. M., Nurse, M. A., & Stefanyshyn, D. J. (1999). Shoe inserts and orthotics for sport and physical activities. *Medicine & Science in Sports & Exercise, 31*(Supplement), S421–S428.

Nigg, B. M., Stergiou, P., Cole, G., Stefanyshyn, D., Mündermann, A., & Humble, N. (2003). Effect of shoe inserts on kinematics, center of pressure, and leg joint moments during running. *Medicine & Science in Sports & Exercise*, *35*(2), 314–319.

Nigg, B. M., Baltich, J., Hoerzer, S., &; Enders, H. (2015). Running shoes and running injuries: mythbusting and a proposal for two new paradigms: 'preferred movement path' and 'comfort filter.' British Journal of Sports Medicine, 49(20), 1290–1294.

Noehren, B., Davis, I., & Hamill, J. (2007). ASB Clinical Biomechanics Award Winner 2006: Prospective study of the biomechanical factors associated with iliotibial band syndrome. *Clinical Biomechanics*, *22*(9), 951–956.

Noehren, B., Schmitz, A., Hempel, R., Westlake, C., & Black, W. (2014). Assessment of strength, flexibility, and running mechanics in men with iliotibial band syndrome. *The Journal of Orthopaedic and Sports Physical Therapy*, *44*(3), 217–222.

Novick, A., & Kelley, D. L. (1990). Case study: position and movement changes of the foot with orthotic intervention during the loading response of gait. *Journal of Orthopaedic & Sports Physical Therapy*, *11*(7), 301–312.

Nunes, G. S., de Oliveira Silva, D., Pizzari, T., Serrão, F. V., Crossley, K. M., & Barton, C. J. (2019). Clinically measured hip muscle capacity deficits in people with patellofemoral pain. *Physical Therapy in Sport: Official Journal of the Association of Chartered Physiotherapists in Sports Medicine*, *35*, 69–74

Okunuki, T., Koshino, Y., Yamanaka, M., Tsutsumi, K., Igarashi, M., Samukawa, M., Saitoh, H., & Tohyama, H. (2019). Forefoot and hindfoot kinematics in subjects with medial tibial stress syndrome during walking and running. *Journal of Orthopaedic Research*, *37*(4), 927–932.

Oliveira, L. V. de, Saad, M. C., Felício, L. R., & Grossi, D. B. (2014). Muscle strength analysis of hip and knee stabilizers in individuals with patellofemoral pain Syndrome. *Fisioterapia e Pesquisa*, 21, 327–332.

Pedisic, Z., Shrestha, N., Grgic, J., Kovalchik, S., Stamatakis, E., Liangruenrom, N., Titze, S., Biddle, S., Bauman, A. E., Virgile, A., & Oja, P. (2020). Is running associated with a lower risk of all-cause, cardiovascular and cancer mortality, and is more better? A systematic review and meta-analysis. *British Journal of Sports Medicine*, *54*(13), 817–818.

Pohl, M. B., Mullineaux, D. R., Milner, C. E., Hamill, J., & Davis, I. S. (2008). Biomechanical predictors of retrospective tibial stress fractures in runners. *Journal of Biomechanics, 41*(6), 1160–1165.

Pohl, M. B., Hamill, J., & Davis, I. S. (2009). Biomechanical and anatomic factors associated with a history of plantar fasciitis in female runners. Clinical Journal of Sport Medicine: *Official Journal of the Canadian Academy of Sport Medicine, 19*(5), 372–376.

Powers, C. M. (2003). The influence of altered lower-extremity kinematics on patellofemoral joint dysfunction: a theoretical perspective. *Journal of Orthopaedic & Sports Physical Therapy,* 33(11), 639-646

Powers, C. M., Chen, P.-Y., Reischl, S. F., & Perry, J. (2002). Comparison of foot pronation and lower extremity rotation in persons with and without patellofemoral pain. *Foot & Ankle International*, *23*(7), 634–640.

Reinking, M. F., Austin, T. M., Richter, R. R., & Krieger, M. M. (2016). Medial Tibial Stress Syndrome in Active Individuals: A Systematic Review and Meta-analysis of Risk Factors. Sports Health, 9(3), 252–261.

Ribeiro, A. P., Trombini-Souza, F., Tessutti, V., Lima, F. R., de Camargo Neves Sacco, I., & João, S. M. A. (2011). Rearfoot alignment and medial longitudinal arch configurations of runners with symptoms and histories of plantar fasciitis. *Clinics, 66*(6), 1027–1033.

Rice, H., & Patel, M. (2017). Manipulation of foot strike and footwear increases Achilles tendon loading during running. *The American Journal of Sports Medicine*, *45*(10), 2411–2417.

Richter, R. R., Austin, T. M., & Reinking, M. F. (2011). Foot orthoses in lower limb overuse conditions: a systematic review and meta-analysis-critical appraisal and commentary. *Journal of Athletic Training*, *46*(1), 103–106.

Ring, K., & Otter, S. (2014). Clinical efficacy and cost-effectiveness of bespoke and prefabricated foot orthoses for plantar heel pain: A prospective cohort study. *Musculoskeletal Care*, *12*(1), 1–10.

Rodrigues, P., Chang, R., TenBroek, T., van Emmerik, R., & Hamill, J. (2015). Evaluating the coupling between foot pronation and tibial internal rotation continuously using vector coding. *Journal of Applied Biomechanics, 31*(2), 88–94.

Scheerder, J., Breedveld, K., & Borgers, J. (2015). *Running across Europe: The rise and size of one of the largest sport markets*. Palgrave Macmillan.

Self, B. P., & Paine, D. (2001). Ankle biomechanics during four landing techniques. *Medicine and Science in Sports and Exercise, 33*(8), 1338–1344.

Sinclair, J. K., Chockalingam, N., & Vincent, H. (2014a). Gender differences in multi-segment foot kinematics and plantar fascia strain during running. *Foot and Ankle Online Journal*, *15*(4).

Sinclair, J., Isherwood, J., & Taylor, P. J. (2014b). Effects of foot orthoses on Achilles tendon load in recreational runners. *Clinical Biomechanics*, *29*(8), 956–958.

Sinclair J, Naemi R, Chockalingam N, Greenhalgh A. (2014c). Investigation into the kinetics and kinematics during running in the heelless shoe. *Footwear Science, 6*; 1–7

Sinclair, J., & Selfe, J. (2015a). Sex differences in knee loading in recreational runners. *Journal of Biomechanics*, *48*(10), 2171–2175.

Sinclair, J., Isherwood, J., & Taylor, P. J. (2015b). The effects of orthotic intervention on multisegment foot kinematics and plantar fascia strain in recreational runners. *Journal of Applied Biomechanics*, *31*(1), 28–34.

Sinclair, J., Richards, J. D., & Shore, H. (2016). Effects of semi-custom and off-the-shelf orthoses on Achilles tendon and patellofemoral kinetics in female runners. *Baltic Journal of Health and Physical Activity*, *8*(4), 7–15.

Smith, L. S., Clarke, T. E., Hamill, C. L., & Santopietro, F. (1986). The effects of soft and semi rigid orthoses upon rearfoot movement in running. *Journal of the American Podiatric Medical Association*, *76*(4), 227–233.

Sneyers, C. J., Lysens, R., Feys, H., & Andries, R. (1995). Influence of malalignment of feet on the plantar pressure pattern in running. *Foot & Ankle International*, *16*(10), 624–632.

Stacoff, A., Reinschmidt, C., Nigg., B., Bogert, A., Lundberg, A., Denoth, J., Stussi, E. (2000). Effects of foot orthoses on skeletal motion during running. *Clinical Biomechanics*, *15*, 54-64.

Stanitski, C. L., McMaster, J. H., & Scranton, P. E. (1978). On the nature of stress fractures. *The American Journal of Sports Medicine*, *6*(6), 391–396.

Synovate (2008). *Reasons to run survey*. www.everythingaboutrunning.asics.eu.

Taunton, J. E. (2002). A retrospective case-control analysis of 2002 running injuries. *British Journal of Sports Medicine*, *36*(2), 95–101.

Taunton, J. E., Ryan, M. B., Clement, D. B., McKenzie, D. C., & Lloyd-Smith, D. R. (2002). Plantar fasciitis: A retrospective analysis of 267 cases. *Physical Therapy in Sport, 3*(2), 57–65.

Tong, J. W. K., & Kong, P. W. (2013). Association between foot type and lower extremity injuries: Systematic literature review with meta-analysis. *Journal of Orthopaedic & Sports Physical Therapy, 43*(10), 700–714.

Van Bottenburg, M., Scheerder, J., & Hover, P.L. (2010). Don't miss the next boat: Europe's opportunities and challenges in the second wave of running. *New Studies in Athletics, 25*(3), 125-143.

van der Worp, M. P., ten Haaf, D. S. M., van Cingel, R., de Wijer, A., Nijhuis-van der Sanden, M. W. G., & Staal, J. B. (2015). Injuries in runners; A systematic review on risk factors and sex differences. *PLoS ONE, 10*(2), e0114937.

van Gent, R. N., Siem, D., van Middelkoop, M., van Os, A. G., Bierma-Zeinstra, S. M., & Koes, B. W. (2007). Incidence and determinants of lower extremity running injuries in long distance runners: a systematic review. *British Journal of Sports Medicine, 41*(8), 469-480.

van Mechelen, W. (1992). Running Injuries: A review of the epidemiological literature. *Sports Medicine*, 14(5), 320–335.

Wang, L., Xian Li, J., Hong, Y., & He Zhou, J. (2010). Changes in heel cushioning characteristics of running shoes with running mileage. *Footwear Science, 2*(3), 141–147.

Warren, B. L. (1990). Plantar fasciitis in runners. *Sports Medicine*, *10*(5), 338–345.

Wegener, C., Burns, J., & Penkala, S. (2008). Effect of neutral-cushioned running shoes on plantar pressure loading and comfort in athletes with cavus feet: A crossover randomized controlled trial. *The American Journal of Sports Medicine*, *36*(11), 2139–2146.

Whiting, W. C., & Zernicke, R. F. (2008). *Biomechanics of Musculoskeletal Injury* (2nd ed.). Human Kinetics.

Williams, D. S., McClay, I. S., & Hamill, J. (2001a). Arch structure and injury patterns in runners. *Clinical Biomechanics, 16*(4), 341–347.

Williams, D. S., McClay, I. S., Hamill, J., & Buchanan, T. S. (2001b). Lower extremity kinematic and kinetic differences in runners with high and low arches. *Journal of Applied Biomechanics, 17*(2), 153–163.

Willson, J. D., & Davis, I. S. (2008). Lower extremity mechanics of females with and without patellofemoral pain across activities with progressively greater task demands. *Clinical Biomechanics (Bristol, Avon)*, *23*(2), 203–211.

Yagi, S., Muneta, T., & Sekiya, I. (2013). Incidence and risk factors for medial tibial stress syndrome and tibial stress fracture in high school runners. Knee Surgery, Sports Traumatology, Arthroscopy, 21(3), 556–563.

Yates, A., Shisslak, C. M., Allender, J., Crago, M., & Leehey, K. (1992). Comparing Obligatory to Nonobligatory Runners. *Psychosomatics, 33*(2), 180–189.

Zadpoor, A. A., & Nikooyan, A. A. (2011). The relationship between lower-extremity stress fractures and the ground reaction force: A systematic review. Clinical Biomechanics, 26(1), 23–28.

CHAPTER 3. BIOMECHANICAL AND COMFORT ANALYSES ON THE USE OF COMMERCIAL INSOLES WHILE WALKING AND RUNNING

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Modified from a manuscript to be submitted to *Clinical Biomechanics*

Abstract

Background: Incidence rates of running injuries are high. Previous research has indicated that the use of prefabricated insoles may be beneficial for altering kinematic and kinetic patterns that cause running injuries. The purpose of this study was to evaluate how prefabricated insoles affect kinematics, kinetics, plantar pressure, and perceived comfort during walking and running.

Methods: Twenty-one (16 female, 5 male) participants walked and ran with their regular running shoes and with two types of prefabricated insoles. A motion capture system and force platforms were used to collect kinematic and kinetic data. Pressure inserts were used to collect plantar pressures, and a comfort questionnaire was used to measure levels of perceived comfort.

Results: The Currex insole reduced ankle eversion and peak midfoot pressure during walking, while reducing peak toe and average whole foot pressure during running. However, the regular running shoe was still preferred over the Currex insole by a higher percentage of participants, 55% to 35%. The PowerStep insole also reduced ankle eversion and peak midfoot pressure during walking, while reducing Achilles tendon load and ankle inversion moment during running. However, the PowerStep insole had lower comfort ratings than the regular running shoe and Currex insole.

Conclusion: In a combined evaluation of kinematic, kinetic, and plantar pressure data with comfort scores, there was a mix of potential benefits, drawbacks, and perceptions of insole use.

These conflicting results may indicate that prefabricated insoles are most likely to be beneficial when matched to an individual's biomechanical needs, comfort preferences, and intended use.

Introduction

Running as a sport or recreational activity has grown significantly in popularity since the 1970's (Schreeder et al., 2015). One of the biggest drawbacks to the sport that is otherwise a cost effective lifestyle medicine (Lee et al., 2017) is the likelihood of sustaining a running related injury. Incidence rates of lower extremity injuries may range anywhere from 19-79% (van Gent et al., 2007). Lower extremity injuries to the foot, ankle, calf, and knee account for approximately 75% of running injuries while injuries to the upper leg, hip and pelvis, and lower back make up the remaining 25% (Fields, 2011). Currently, specific injuries that demonstrate the highest prevalence in the sport include patellofemoral pain syndrome (PFPS), medial tibial stress syndrome (MTSS), plantar fasciitis, iliotibial band syndrome (ITBS), Achilles tendinopathy, and stress fractures/fractures (Kakouris et al., 2021).

A combination of intrinsic and extrinsic risk factors likely predispose runners to injury. Common intrinsic risk factors include runner demographics such as age and biological sex, anatomical structure, history of previous injury, muscular deficits, kinematic patterns, and kinetic patterns. The change in running demographics since the 1970's has led to a running population that is more female, older, and runs recreationally (Andersen, 2021). Female runners have been shown to have higher rates of injury to the knee and bone, while males have been shown to be more likely to develop Achilles tendinopathies and plantar fasciitis (Reinking et al., 2017; Taunton et al., 2002; Hollander et al., 2021). Age has also been associated with type of injury a runner may be more susceptible to. Older runners have a higher prevalence of injuries to the Achilles and younger runners suffer more injuries to the knee and leg (McKean et al., 2006).

Anatomical structure such as Q-angle measurement or pes cavus and pes planus foot types have been associated with greater risk of running injury. Larger Q-angles in females puts female runners at greater risk for developing PFPS or ITBS compared to their male counterparts (Ferber et al., 2003). Similarly, those with pes cavus or pes planus foot types have been identified as being at higher risk for developing a variety of injuries. Some studies have established different injury patterns based on classification of foot type (Williams et al., 2001a; Williams et al. 2001b) while results of other studies suggest that having either arch deformity puts runners at higher risk of injury (Pohl et al., 2009; Riberio et al., 2011).

Kinematic patterns associated with high rates of running injury include excessive eversion, pronation, tibial internal rotation (TIR), hip adduction, hip internal rotation, and various degrees of knee flexion angles. It should be noted that much inconsistency amongst these variables remains across the literature suggesting that specific kinematic patterns are not universal in causing running injuries but may be more applicable to specific subpopulations. Excessive eversion and pronation of the foot has been directly linked to the development of MTSS (Okunuki et al., 2019), and stress fractures (Milgrom et al., 2007; Pohl et al., 2008). Due to the mechanical coupling of the leg and foot, calcaneal eversion can result in significant TIR leading to Achilles tendinopathies (Clement et al., 1984) and PFPS (Rodriguez et al., 2014). The mechanical coupling as a cause for PFPS and ITBS has been highly controversial throughout the literature. Many studies find that even without abnormalities in rearfoot eversion or pronation, abnormal tibial rotation is linked to both PFPS (Arazpour et al., 2016) and ITBS (Noehren et al., 2007).

Runners who display greater hip adduction have been linked to the development of PFPS (Dierks et al., 2008; Willson & Davis, 2007), ITBS (Ferber et al., 2010; Noehren et al., 2007), and tibial stress fractures (Pohl et al., 2008; Milner et al., 2010). Still, studies remain inconclusive on these relationships between hip adduction on PFPS and ITBS (Dierks et al., 2011; Baker et al., 2010). Greater hip internal rotation has also been associated with PFPS (Meira et al., 2011), ITBS (Ferber et al. 2003; Noehren et al., 2014), and MTSS (Yagi et al., 2003).

Kinetic patterns associated with running injuries include extension, abduction, tibial rotation, and inversion moments. Most notably, forces such as ground reaction force (GRF) and joint contact forces are often associated with the development of running injuries. Differences in maximum braking forces have been shown in runners with PFPS (Messier et al., 1991), ITBS (Messier et al., 1995), and Achilles tendinopathies (Baur et al., 2004). Excessive loading and strain on both the Achilles (Rice & Patel, 2017) and plantar fascia (Pohl et al., 2009; Johnson et al., 2020) have also been highly correlated to the development of injury.

The use of insoles and orthotics has become widely popular for the treatment or prevention of foot and knee pathologies. Both devices primarily serve to align the skeleton, improve impact cushioning, and/or provide improved comfort (Nigg et al., 1999). Prefabricated insoles have been shown to be more cost effective (Ring & Otter, 2014) and perform to at least equal standards as custom fit orthotics both biomechanically and in perceived comfort ratings (Gil-Calvo et al., 2020; Lucas-Cuevas et al., 2014b). This suggests that prefabricated insoles stand as a reasonable alternative to custom orthotics.

Prefabricated insoles effect the closed kinematic chain by adjusting excessive rearfoot eversion and pronation (Smith et al., 1986; Novick & Kelley, 1990; Majumdar et al.,2013). Insoles have been found to reduce frontal plane ankle movement in studies involving runners with PFPS (Eng & Pierrynowski, 1994) and plantar fasciitis (Sinclair et al., 2015b). However, some studies have found no significant effect between insole use and rearfoot eversion (GilCalvo et al., 2020; Nawoczenski et al., 1995, Dixon, 2007). When observing the coupling mechanism between calcaneal inversion and eversion with tibial rotation, studies have found significant relationships (Mündermann et al., 2003). However, other studies have reported no differences in ankle inversion while observing differences in tibial rotation (Stacoff et al., 2008; Nawoczenski et al., 1995). Further up the chain, insoles have also been shown to reduce the amount of hip range of motion in the transverse and frontal planes (Braga et al., 2019).

The primary variables used to evaluate kinetic effects of insoles include loading rates and peak ground reaction forces. However, results from these studies are rather inconsistent. Studies exist supporting the use of insoles to attenuate the role of impact and contact forces on running injury (Dixon, 2007; Landorf et al., 2006; Sinclair et al., 2016) while others report no or detrimental effects with the use of insoles (Mündermann et al., 2003; Sinclair et al., 2016). Other proposed kinetics changes with the use of insoles include reduced ankle inversion moment (Mündermann et al., 2003; Nigg et al., 2003) and both reductions and increases for knee external rotation moment (Mündermann et al., 2003; Nigg et al., 2003).

Perceptions of comfort have been introduced as an important factor in the successful use of insoles. Studies based on comfort have found significant decreases in frequency of injury for insole conditions which participants found more comfortable (Mündermann et al., 2001). It has also been shown that more flexible, softer products that continue to offer structural support such as a semi-rigid insole have been found to be preferred by users than hard or rigid insoles (Braunstein et al., 2015; Mündermann et al., 2002). One measurement that has been used to quantify the comfort of insoles is plantar pressure distribution of the foot. This relationship remains unclear as studies have found correlations between plantar pressure and comfort (Chen et al., 1994; Wegener et al. 2008) while others show lack of evidence for such correlations (Jordan & Bartlett, 1995; Braunstein et al., 2015).

No study known by the authors to date has performed a biomechanical analysis of prefabricated insoles based on the combined evaluation of kinematic, kinetic, and plantar pressure data with perceived comfort scores. In order to fill the gap in knowledge participants in this study will be assessed based on both quantitative kinematic, kinetic, and plantar pressure data with the added qualitative assessment of perceived comfort. It is hypothesized that prefabricated insoles will provide improved subjective comfort compared to the baseline running shoe. When comparing types of prefabricated insoles, it is hypothesized that a softer more flexible Currex insoles will result in improved comfort and beneficial biomechanical changes compared to more rigid PowerStep insoles. Finally, increases in perceived comfort are hypothesized to be associated with beneficial biomechanical changes.

Methods

Participants

A power analysis was performed for sample size estimation, based on data from Dixon (2007) comparing commercially available insoles to a control condition. The effect size in this study was considered to be medium at 0.5. With a significant criteria of $\alpha = .05$, power = .95, the minimum sample size needed was 21 participants. Twenty-one (16 female and 5 male) recreational and competitive runners were recruited for this study (Table 2.1). Participants were recruited from university courses, clubs, and departmental email lists. Inclusion criteria for participants required them to be 18 years of age or older and currently running at least an average of 10 miles per week. Exclusion criteria for participants included suffering any lower extremity injury in the past 3 months, undergoing any lower extremity surgery in the past year, and/or currently using orthotics. Prior to data collection, participants provided informed consent and completed a questionnaire asking for their age, body mass, height, weekly mileage, years running, type of runner (recreational or competitive), shoe size of their current running shoe, and general history of lower extremity injury. This study was approved by the Institutional Review Board at Iowa State University (ID: 21-437).

Table 3.1 Participant demographics and training characteristics expressed in mean ± standard deviation.

		Age (years)	**Mass (kg)**	**Height (m)**	**Average Weekly Mileage**	**Years Running**
Total	n=21	25 ± 9	66 ± 9	1.68 ± 0.09	17 ± 7	11 ± 8
Sex	Female n=16	24 ± 8	64 ± 9	1.65 ± 0.05	15 ± 4	10 ± 7
	Male n=5	30 ±1	71 ± 2	1.80 ± 0.06	22 ± 2	14 ± 3
Type of Runner	Recreational n=14	24 ± 9	65 ± 10	1.67 ± 0.05	16 ± 4	9 ± 8
	Competitive n=7	26 ± 10	67 ± 5	1.75 ± 0.11	22 ± 10	15 ± 8

Data Collection

A twelve camera motion capture system (Qualisys, Gothenburg, Sweden) was used to capture three-dimensional kinematic data at a sampling frequency of 240 Hz. Ground reaction forces were captured at a sampling frequency of 1200 Hz using force platforms (AMTI, Watertown, MA) mounted in the floor of a 30-meter runway.

Participants were asked to wear tight fitting clothing and their own running shoes. Prior to data collection, participants completed a five minute warmup on a treadmill at a self-selected running pace. After the warmup was complete, participants were provided two adjustment periods to become familiar with the two insoles they would use for the data collection. Each adjustment period for the two insoles was three minutes in duration. Participants walked and jogged during each adjustment period to simulate the movements they would perform during testing. The adjustment periods for each participant followed the randomized order of the insole conditions that would be tested during the data collection.

Following the warmup and adjustment periods, participants were fitted with 21 retroreflective markers. Markers were attached to the dominant leg and torso on the first metatarsal, fifth metatarsal, heel, medial and lateral malleoli, anterior calf, lateral calf, medial and lateral tibial epicondyles, anterior thigh, lateral thigh, left and right greater trochanters, left and right anterior superior iliac spines (ASIS), left and right posterior superior iliac spines (PSIS), sacrum, left and right acromion, and the cervicale. Markers were used to create segments for the foot, shank, thigh, pelvis, and trunk.

Participants performed a static trial wearing their running shoes by standing on the force platform with arms raised and crossed in front of their chest. The static trial was performed to determine the participant’s static alignment with and without shoes. The static trial was collected for two seconds.

There were three conditions for each participant: original shoe, PowerStep® PULSE® Performance (PowerStep), and CURREX RUNPRO™ (Currex) Insoles. The PowerStep insole is a full length semi-rigid insole made from a polypropylene support shell with a PORON foam top layer and EVA base. The Currex insole is a full length semi-rigid insole constructed from EVA, PORON, and patented Dynamic Arch Technology. Both insoles are marketed to improve comfort and support of the shoe and to prevent and relieve pain of the foot. Insoles were donated by Achilles Running Shop (Mentor, OH) and matched to the size of the participant’s running shoe.

Within each of the three conditions, participants completed both walking and running trials. The order of conditions and the order of walking and running within the condition were randomized between participants to control for potential effects of fatigue and learning on running and walking mechanics. Participants were instructed to place each insole being tested directly on top of the original insole of their running shoe. For each condition, plantar pressure inserts (XSENSOR, Calgary, AB) were placed in the shoes between the original or tested insole and the participant's feet.

Dynamic trials were performed over a 30-meter runway through the calibration volume of the Qualysis cameras. Participants were instructed to walk at their preferred walking pace and to run at a velocity that was representative of their typical training pace. Conditions were completed when three successful trials under each condition were recorded for a total of eighteen dynamic trials (three conditions x three trials for walking plus three conditions x three trials for running). A successful walking or running trail was defined as striking the force platform with the entire dominant foot without any visual targeting. Running velocity was monitored by calculating the average velocity of the sacral marker during stance phase. Average running velocity was observed to be within ± 3% of preferred running velocity between the conditions.

Following completion of the dynamic trials, participants completed a comfort questionnaire asking them to rank the forefoot, midfoot, and rearfoot comfort of the three conditions (original shoe, PowerStep insole, and Currex insole). The questionnaire was ranked on a scale of 1-5, with 1 being "uncomfortable" and 5 being "comfortable". Overall scores were calculated by summing the comfort scores from the forefoot, midfoot, and rearfoot. In addition, participants were asked to choose their preference between the conditions based on comfort, with a "No Preference" option also provided.

Data Analysis

MatLab (MathWorks, Natick, MA) programs were developed to calculate kinematic and kinetic variables from the motion and force data collected. Data were analyzed throughout the stance phase. The stance phase was defined as first foot contact when the vertical ground reaction force exceeded 5% of body weight to toe off when the vertical ground reaction force fell below 5% of body weight.

Joint centers for the ankle, knee, and hip were calculated. The ankle joint center was identified as the midpoint between the markers at the lateral and medial malleoli. The knee joint center was identified as the midway point between the markers at the lateral and medial femoral epicondyles. The right hip joint center was calculated as 25% of the distance between markers from the right to left greater trochanters. Kinematic data were filtered with a fourth order low pass Butterworth filter with a 15 Hz cutoff frequency. Joint angles were calculated using Euler/Cardan equations in the rotation sequence of flexion/extension, abduction/adduction, and internal/external rotation.

Joint moments were calculated using inverse dynamics. A cutoff frequency of 15 Hz was used for force plate data. de Leva's (1996) anthropometric model was used to estimate segment masses, center of mass, and moments of inertia. Joint moments were normalized to body mass and calculated as internal moments with the exception of knee varus. Knee varus is reported as an external joint moment due to the limited muscle support in this plane of movement.

Average and instantaneous Achilles tendon load (ATL) was estimated by dividing the plantar flexion moment (PFM) by the estimated Achilles tendon moment arm (atma) in centimeters. The Achilles tendon moment arm is a function of ankle sagittal plane angle (θ) (Self & Paine, 2001; Sinclair et al., 2014).

$$ATL = PFM / atma$$

$$atma = -0.5910 + (0.08297)\theta - (0.0002606)\theta^2$$

where θ is 90 degrees when the angle is in a neutral position.

Statistical Analysis

Maximum values for kinematic, kinetic, and pressure variables were averaged across three trials for each condition. A repeated measures MANOVA within subjects comparison of insole condition was performed on all joint angle, ground reaction force, plantar pressures of the heel, midfoot, metatarsal, and toe regions of the foot, ATL, and comfort questionnaire variables. A significance value of alpha = .05 was used. Tukey post hoc comparisons were used to test for significant differences between conditions when significant main effects were detected. All statistical analyses were run in SPSS (IBM, Armonk, NY).

Results

Results of the MANOVAs indicated that there were significant within-subjects main effects for the insole condition on walking kinematics and kinetics ($p = 0.033$), running kinematics and kinetics ($p = 0.035$), walking plantar pressure ($p < 0.001$), running plantar pressure ($p < 0.001$), and walking/running comfort ($p < 0.001$).

Kinematics

The ANOVAs indicated that the insole condition while walking produced significant differences in peak ankle dorsiflexion ($p < 0.001$), peak ankle eversion ($p = 0.001$), and peak knee flexion ($p = 0.026$; Table 3.2). Peak ankle dorsiflexion was significantly lower with the Currex ($p < 0.001$) and PowerStep insoles ($p = 0.004$) than with the regular shoe. Peak ankle eversion was significantly lower with the Currex ($p = 0.013$) and the PowerStep insoles ($p = 0.002$) than with the regular shoe. Peak knee flexion was significantly lower with the regular shoe than with the Currex insole ($p = 0.018$; Figure 1).

Table 3.1. Kinematic variables as a function of insole condition during walking. Average peak values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold and noted as superscripts: a = significantly lower than Regular Shoe, b = significantly lower than Currex.

Angle (degrees)	Regular Shoe	Currex	PowerStep
Ankle Dorsiflexion	10.1 ± 5.3	**9.2 ± 4.4**[a]	**7.8 ± 4.9**[a]
Ankle Eversion	6.5 ± 5.9	**4.7 ± 3.5**[a]	**4.3 ± 3.6**[a]
Knee Flexion	**38.4 ± 3.7**[b]	39.4 ± 3.6	39.2 ± 3.8
Knee Valgus	4.4 ± 3.3	4.5 ± 3.5	4.1 ± 3.2
Hip Adduction	8.5 ± 8.8	8.0 ± 8.9	7.6 ± 9.3
Hip Internal Rotation	6.8 ± 9.6	6.2 ± 9.6	7.0 ± 9.0

The ANOVAs indicated that the insole condition while running produced significant differences in peak ankle dorsiflexion ($p < 0.003$; Table 3.3). Peak ankle dorsiflexion was significantly lower with the Currex ($p = 0.023$) and PowerStep ($p = 0.004$) insoles than with the regular shoe (Figure 1).

Table 3.2 Kinematic variables as a function of insole condition during running. Average peak values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold and noted as superscripts: a = significantly lower than Regular Shoe.

Angle (degrees)	Regular Shoe	Currex	PowerStep
Ankle Dorsiflexion	13.9 ± 6.7	**12.1 ± 5.7**[a]	**10.7 ± 5.7**[a]
Ankle Eversion	10.7 ± 6.1	9.6 ± 3.6	9.5 ± 5.3
Knee Flexion	44.9 ± 9.6	44.2 ± 10.5	43.3 ± 3.5
Knee Valgus	1.9 ± 2.6	1.8 ± 2.4	1.9 ± 2.6
Hip Adduction	1.2 ± 7.1	1.0 ± 6.8	1.2 ± 7.6
Hip Internal Rotation	7.1 ± 9.7	8.5 ± 9.0	7.5 ± 9.2

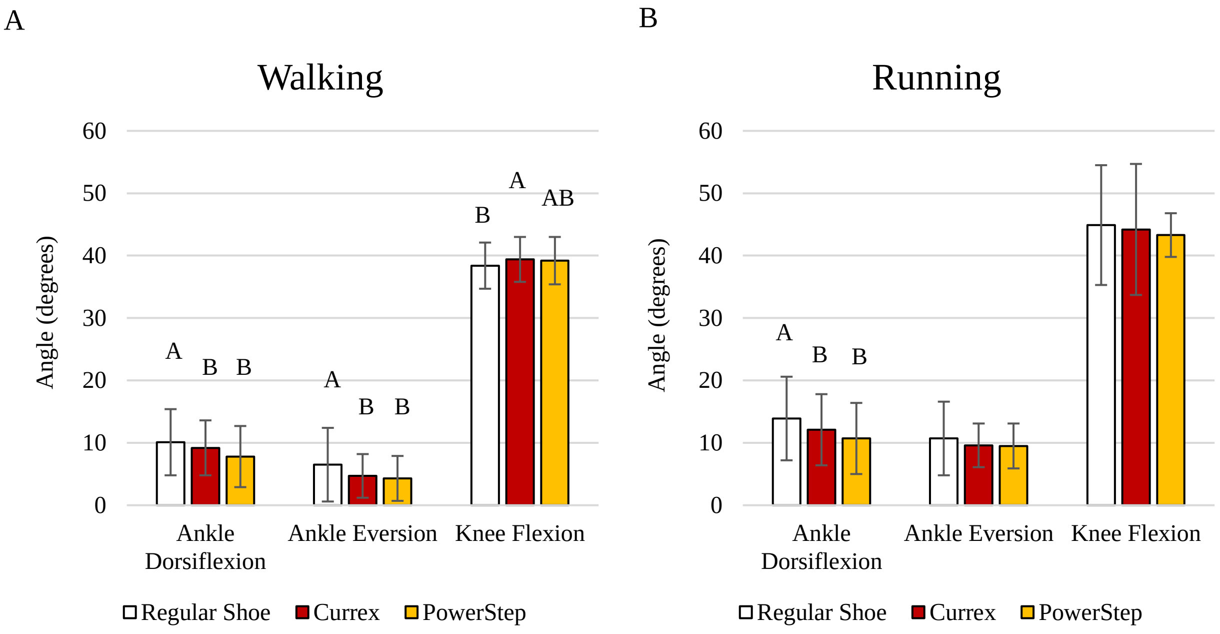

Figure 1. Kinematics as a function of insole condition during A) walking and B) running.

Kinetics

The ANOVAs did not indicate that insole condition produced any significant differences for the kinetic variables during walking (Table 3.4).

Table 3.3. Kinetic variables as a function of insole condition during walking. Average maximum values ± standard deviations.

GRF (BW)	**Regular Shoe**	**Currex**	**PowerStep**
GRF	1.25 ± 0.09	1.22 ± 0.04	1.22 ± 0.07
ATL (BW)	**Regular Shoe**	**Currex**	**PowerStep**
Peak ATL	2.79 ± 0.69	2.79 ± 0.39	2.76 ± 0.38
Peak Moment (Nm/kg)	**Regular Shoe**	**Currex**	**PowerStep**
Ankle Plantar Flexion	1.42 ± 0.35	1.42 ± 0.20	1.42 ± 0.19
Ankle Inversion	0.18 ± 0.11	0.16 ± 0.10	0.15 ± 0.09
Knee Extension	0.76 ± 0.35	0.70 ± 0.25	0.72 ± 0.31
Knee External Varus	0.11 ± 0.06	0.11 ± 0.06	0.10 ± 0.05
Hip Extension	3.41 ± 0.45	3.35 ± 0.35	3.31 ± 0.33
Hip Abduction	1.07 ± 0.20	1.09 ± 0.25	1.04 ± 0.18

The ANOVAs indicated that insole condition while running produced significant differences in peak ATL (p = 0.020), peak ankle plantar flexion moment (p = 0.047), and peak ankle inversion moment (p = 0.021; Table 3.4). Peak ATL was significantly lower with the PowerStep insole than with the regular shoe (p = 0.030). Peak ankle plantar flexion moment did not show any significance differences between insole conditions in pairwise comparisons (p = 0.052 and higher). Peak ankle inversion moment was significantly lower with the PowerStep insole than with the regular shoe (p = 0.014) and the Currex insole (p = 0.029; Figure 2).

Table 3.4 Kinetic variables as a function of insole condition during running. Average peak values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold and noted as superscripts: a = significantly lower than Regular Shoe, b = significantly lower than Currex.

GRF (BW)	**Regular Shoe**	**Currex**	**PowerStep**
GRF	2.61 ± 0.26	2.57 ± 0.32	2.55 ± 0.30
ATL (BW)	**Regular Shoe**	**Currex**	**PowerStep**
Peak ATL	4.59 ± 1.03	4.31 ± 0.79	**4.20 ± 0.79**^{a}
Peak Moment (Nm/kg)	**Regular Shoe**	**Currex**	**PowerStep**
Ankle Plantar Flexion	2.46 ± 0.53	2.33 ± 0.44	2.28 ± 0.43
Ankle Inversion	0.43 ± 0.27	0.40 ± 0.22	**0.37 ± 0.23**^{a,b}
Knee Extension	2.76 ± 0.43	2.73 ± 0.59	2.82 ± 0.56
Knee External Varus	0.14 ± 0.12	0.17 ± 0.11	0.14 ± 0.08
Hip Extension	3.48 ± 0.40	3.53 ± 0.61	3.54 ± 0.61
Hip Abduction	2.15 ± 0.33	2.17 ± 0.54	2.17 ± 0.33

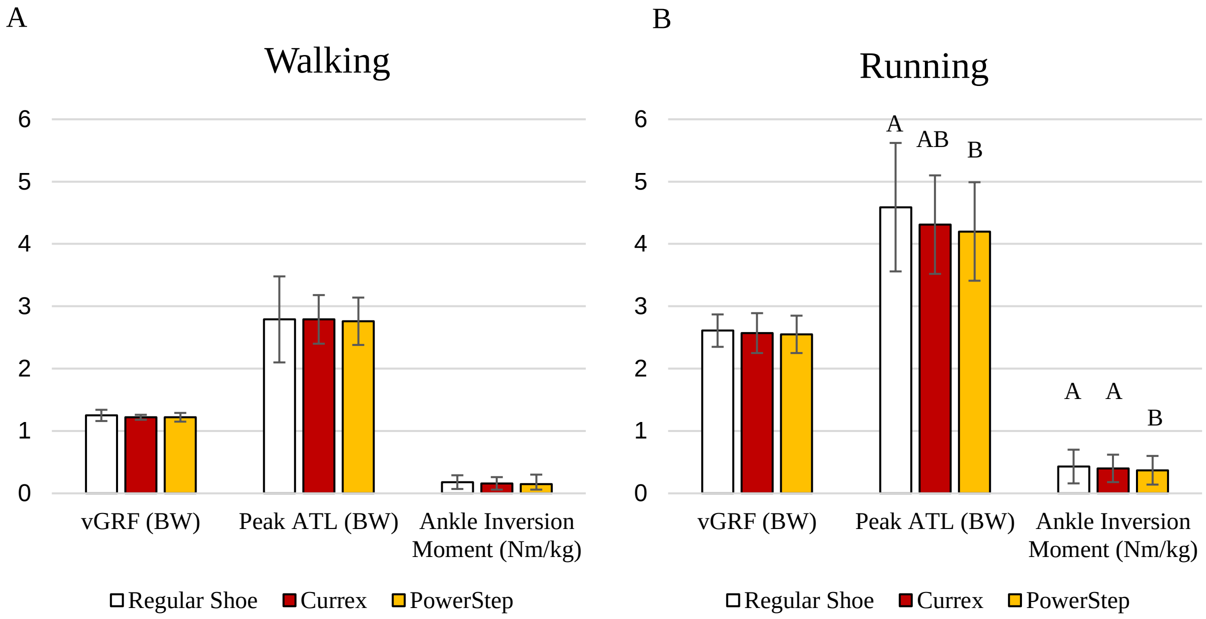

Figure 2. Kinetics as a function of insole during A) walking and B) running.

Plantar Pressure

The ANOVAs indicated that the insole condition while walking produced significant differences in peak heel pressure (p = 0.004), average midfoot pressure (p = 0.004), and peak midfoot pressure (p < 0.001; Table 3.6). Peak heel pressure for the PowerStep insole was significantly lower than both the regular shoe (p = 0.004) and Currex insole (p = 0.015). Average midfoot pressure was significantly lower for the regular shoe condition than the PowerStep insole (p = 0.002). Peak midfoot pressure was significantly lower for both the Currex (p < 0.001) and PowerStep (p = 0.008) insoles than the regular shoe condition (Figure 3).

Table 3.5 Plantar pressure as a function of insole condition during walking. Average values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold font and noted as superscripts: a = significantly lower than Regular Shoe, b = significantly lower than Currex, c = significantly lower than PowerStep.

Pressure (PSI)	Regular Shoe	Currex	PowerStep
Average Whole	6.1 ± 1.1	5.8 ± 1.3	5.8 ± 1.0
Peak Whole	34.9 ± 10.3	35.1 ± 10.4	36.3 ± 11.1
Average Heel	6.5 ± 2.1	6.2 ± 2.5	6.0 ± 2.5
Peak Heel	30.0 ± 10.1	27.8 ± 11.2	**23.1 ± 8.7**^{a,b}
Average Midfoot	**4.1 ± 0.7**^{c}	4.3 ± 1.1	4.8 ± 1.0
Peak Midfoot	18.2 ± 5.8	**15.1 ± 5.9**^{a}	**15.4 ± 5.8**^{a}
Average Metatarsal	5.6 ± 1.6	5.8 ± 1.7	6.3 ± 4.0
Peak Metatarsal	25.0 ± 9.4	25.7 ± 9.5	22.7 ± 9.8
Average Toe	4.8 ± 1.3	4.6 ± 1.5	6.3 ± 6.1
Peak Toe	32.4 ± 10.2	31.4 ± 10.5	34.0 ± 11.3

The ANOVAs indicated that the insole condition while running produced significant differences in average whole pressure ($p = 0.018$), average heel pressure ($p = 0.014$), peak heel pressure ($p = 0.013$), average midfoot pressure ($p < 0.001$), and peak toe pressure ($p = 0.030$; Table 3.7). Average whole foot pressure was significantly lower with the Currex insole compared to the regular shoe ($p = 0.004$). Average heel pressure was significantly lower with the PowerStep insole than with the Currex insole ($p = 0.016$). Peak heel pressure was significantly lower with PowerStep insole compared to the regular shoe condition ($p = 0.008$). Average midfoot pressure was significantly lower during the regular shoe condition than both the Currex insole ($p = 0.006$) and the PowerStep insole ($p < 0.001$). Average midfoot pressure was also significantly lower with the Currex insole than the PowerStep insole ($p = 0.013$). Peak toe pressure was significantly lower with the Currex than with the regular shoe ($p = 0.026$; Figure 3).

Table 3.6 Plantar pressure as a function of insole condition during running. Average values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold font and noted as superscripts: a = significantly lower than Regular Shoe, b = significantly lower than Currex, c = significantly lower than PowerStep

Pressure (PSI)	Regular Shoe	Currex	PowerStep
Average Whole	8.9 ± 2.9	**8.3 ± 2.9**^{a}	8.6 ± 2.6
Peak Whole	51.1 ± 33.1	42.3 ± 11.6	42.3 ± 10.1
Average Heel	5.8 ± 2.9	7.1 ± 3.7	**5.1 ± 2.4**^{b}
Peak Heel	29.5 ± 13.9	26.0 ± 10.5	**23.5 ± 11.0**^{a}
Average Midfoot	**5.2 ± 1.7**^{b,c}	**5.6 ± 1.5**^{c}	6.3 ± 2.1
Peak Midfoot	18.8 ± 5.7	17.3 ± 4.7	19.0 ± 5.1
Average Metatarsal	9.9 ± 3.6	11.8 ± 6.2	9.4 ± 3.0
Peak Metatarsal	45.2 ± 34.6	36.7 ± 13.1	34.9 ± 12.1
Average Toe	8.7 ± 3.5	11.1 ± 8.2	8.5 ± 2.7
Peak Toe	41.4 ± 10.9	**36.2 ± 10.7**^{a}	39.3 ± 8.9

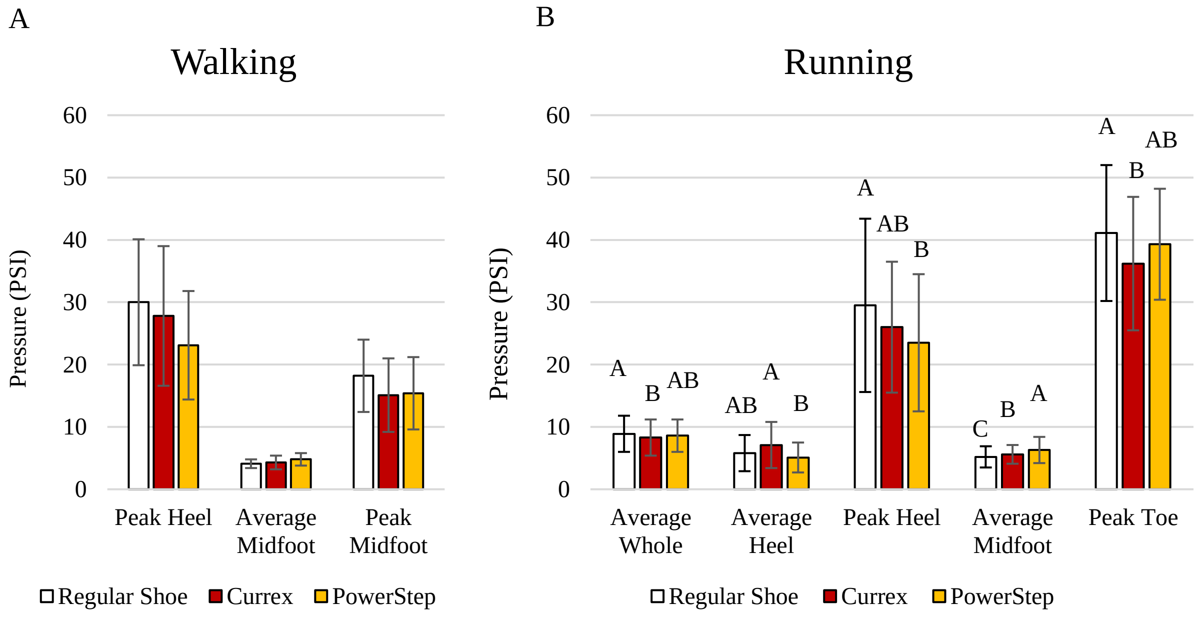

Figure 3. Plantar pressure as a function of insole condition during A) walking and B) running.

Comfort

The ANOVAs indicated that the insole condition produced significant differences in ratings of perceived overall comfort ($p < 0.001$), forefoot comfort ($p < 0.001$), midfoot comfort ($p < 0.001$), and rearfoot comfort ($p < 0.001$; Table 3.8). Overall comfort, midfoot comfort, and rearfoot comfort were significantly higher for the Currex insole and regular shoe than the PowerStep insole (all comparisons $p < 0.001$). Forefoot comfort was also significantly higher for the Currex insole ($p = 0.001$) and regular shoe ($p < 0.001$) than the PowerStep insole. In addition, rearfoot comfort was significantly higher for the regular shoe than the Currex insole ($p = 0.021$; Figure 3).

Table 3.7 Perceived comfort scores as a function of insole condition. Average values ± standard deviations. Significant differences ($p < 0.05$) between conditions are highlighted in bold and noted as superscripts: a = significantly lower than Regular Shoe, b = significantly lower than Currex.

Comfort Score	Regular Shoe	Currex	PowerStep
Overall	13.0 ± 2.1	12.0 ± 2.3	**8.0 ± 2.7**^{a,b}
Forefoot	4.3 ± 1.0	4.0 ± 0.7	**2.9 ± 1.0**^{a,b}
Midfoot	4.2 ± 0.8	4.0 ± 1.1	**2.4 ± 1.2**^{a,b}
Rearfoot	4.5 ± 0.7	**4.0 ± 0.9**^{a}	**2.6 ± 1.2**^{a,b}

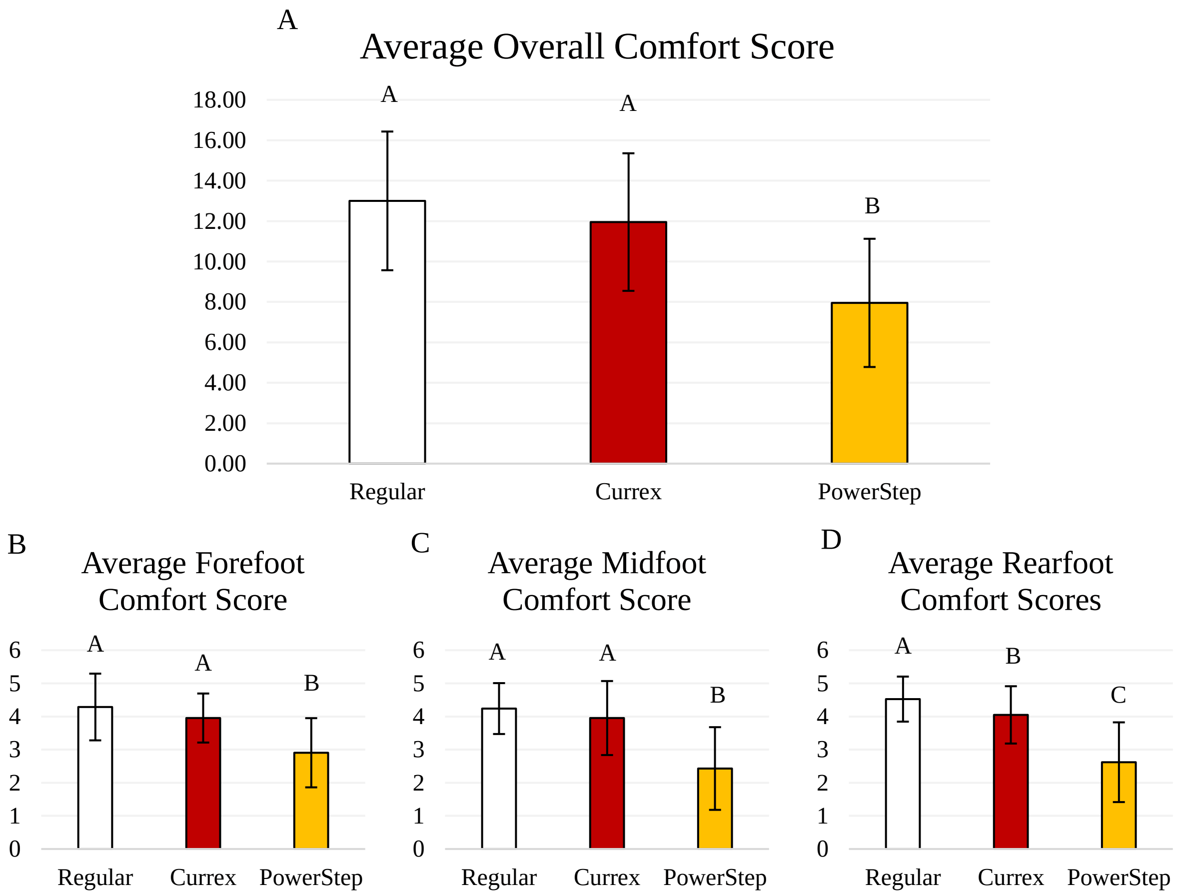

Figure 4. Comfort score as a function of insole condition A) overall and for the B) forefoot, C) midfoot, and D) rearfoot.

In terms of comfort preference, 55% of participants preferred their regular running shoe, 35% of participant preferred the Currex insole, 5% of participants preferred the PowerStep insole, and 5% of participants indicated no preference for insole condition (Figure 5).

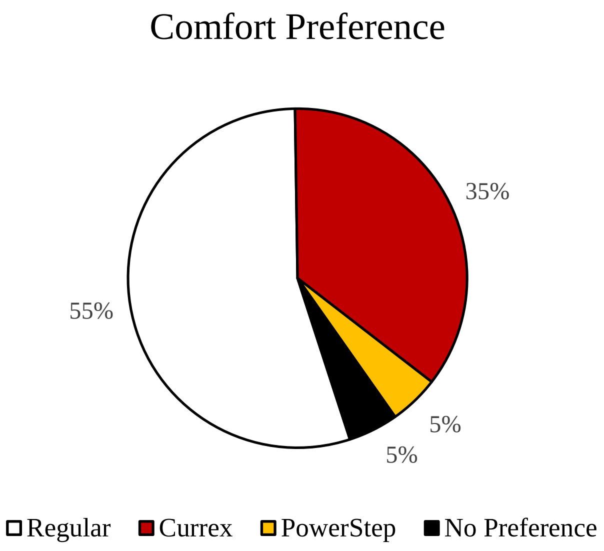

Figure 5. Comfort preference as a function of insole condition.

Discussion

The purpose of this study was to perform a biomechanical analysis of prefabricated insoles based on the combined evaluation of kinematic, kinetic, plantar pressure, and perceived comfort data. It was hypothesized that prefabricated insoles would provide improved subjective comfort compared to the baseline running shoe and a more flexible insole would be preferred to a more rigid insole. In addition, it was hypothesized that a more flexible insole would result in beneficial kinematic and kinetic changes, and reduced pressures compared to a more rigid insole. Results of this study are mixed in terms of biomechanical benefits and drawbacks of prefabricated insoles.

Kinematics

Peak ankle dorsiflexion and ankle eversion were significantly reduced during walking when using the Currex and PowerStep insoles compared to the regular running shoe. This reduction in ankle eversion is a potential benefit during walking as the insoles may prevent excessive rearfoot motion that is often associated with increased risk of injury. However, there were no significant changes in peak ankle eversion when using insoles during running, possibly limiting beneficial applications. Reduced ankle dorsiflexion may be the reason for increased peak knee flexion up the kinetic chain with the Currex insole compared to the regular shoe during walking. Peak ankle dorsiflexion was also significantly reduced during running when using the Currex and PowerStep insoles compared to the regular shoe. However, there were no significant changes in peak knee flexion with the PowerStep insole during walking or with either insole during running.

Kinetics

Peak Achilles tendon load was significantly reduced when using the PowerStep insole compared to the regular running shoe during running. In addition, peak ankle inversion moment was significantly reduced when using the PowerStep insole compared to the Currex insole and regular running shoe. These two differences may provide evidence of potential benefit for the use of the PowerStep insole to reduce the risk of running injuries. Decreased Achilles loading may decrease the risk of developing Achilles tendinopathy, while decreased ankle inversion moments may decrease demand on musculature that controls rearfoot eversion. However, there were no significant differences in kinetic variables when using insoles during walking. Thus, potential kinetic benefits on insoles may be limited to the PowerStep insole and when used during running. In addition, the hypothesis that prefabricated insoles would reduce peak ground reaction forces was not supported during walking or running.

Plantar Pressure

The PowerStep insole significantly reduced average heel pressure compared to the Currex insole during running, and peak heel pressure compared to the regular shoe and Currex insole during walking, plus Currex insole during running. The Currex and PowerStep insoles reduced peak midfoot pressure compared to the regular shoe during walking, and the Currex insole reduced average midfoot pressure compared to the PowerStep insole during running. However, the regular shoe had lower average midfoot pressure than the PowerStep insole during walking and lower average midfoot pressure than both insoles during running. Finally, the Currex insole reduced peak toe and average whole foot pressure compared to the regular shoe during running. Taken together, the Currex insole may provide pressure benefits to the midfoot, toe, and overall foot, while the PowerStep may provide pressure benefits to the heel during walking and running. The hypothesis that prefabricated insoles would reduce peak pressures, particularly the Currex insole, compared to the regular running shoe had mixed support overall.

Comfort

The Currex insole had statistically similar scores compares to the regular running shoe in the midfoot, forefoot, and overall comfort categories The regular running shoe had a significantly improved rearfoot comfort score than the Currex insole. In contrast, the PowerStep insole was rated significantly lower in all comfort categories as compared to the Currex insole and regular shoe. These results are in agreement with findings from Braunstein et al. (2015) regarding the comfort differences between more flexible and more rigid insoles. Reduced comfort scores across all categories may have a detrimental effect on user acceptance of the PowerStep insole, although comfort during walking and running were not differentiated. The hypothesis that prefabricated insoles would have improved comfort compared to the regular running shoe was not supported. However, the hypothesis that the more flexible Currex insole would have improved comfort compared to the more rigid PowerStep insole was supported.

Potential Relationships between Biomechanical Variables and Comfort

The Currex insole reduced ankle eversion and peak midfoot pressure compared to the regular shoe during walking, which could be related to improved rearfoot comfort. However, the PowerStep insole also reduced ankle eversion and peak midfoot pressure, but decreased comfort scores. In addition, the PowerStep insole reduced Achilles tendon load and ankle inversion moment during running and reduced peak heel pressure during walking and running as compared to the regular shoe. However, these potential kinetic benefits for the PowerStep insole did not translate to improved comfort. The regular shoe had lower average midfoot pressure during walking and both the regular shoe and Currex insole had lower average midfoot pressure during running as compared to PowerStep insole. Chen et al. (1994) reported that increased midfoot pressure was more comfortable, which is in contrast to the results of this study. There are inconsistent findings in the literature however, as Wegener et al. (2008) reported that reduced peak pressures improved comfort when comparing neutral cushioned running shoes to a control.

Limitations

One limitation of this study is that only acute effects of insole use can be reported. It is possible that effects of long term wear or fatigue could alter the kinematic and/or kinetic patterns and comfort perceptions of insole use. Secondly, this analysis focuses only on healthy runners. An ideal study would prospectively follow runners to observe different patterns in those who develop running related injuries and those who do not. Further, any potential effect for the use of a pressure insert on top of the insoles being tested was unaccounted for and potentially affected any of the variables measured. The demographics of this study were also heavily skewed towards younger female recreational runners, which may not represent the running population as a whole due to the overall lack of inclusion of older adults. Finally, each participant in this study used the same models of insoles regardless of foot type or gait patterns. Because the optimal choice of insole likely requires an individualized approach, it’s possible that the insoles used in this study did not meet the functional needs of each participant.

Key Points

In a combined evaluation of kinematic, kinetic, and plantar pressure data with comfort scores, there was a mix of potential benefits, drawbacks, and perceptions of insole use. The Currex insole reduced ankle eversion and peak midfoot pressure during walking, while reducing peak toe and average whole foot pressure during running. This insole also improved rearfoot comfort as compared to the regular running shoe. However, the regular running shoe was still preferred over the Currex insole by a higher percentage of participants, 55% to 35%. The PowerStep insole also reduced ankle eversion and peak midfoot pressure during walking, while reducing Achilles tendon load and ankle inversion moment during running. However, the PowerStep insole had lower comfort ratings than the regular running shoe and Currex insole, while only being preferred by 5% of the participants. These conflicting results may indicate that prefabricated insoles are most likely to be beneficial when matched to an individual's biomechanical needs, comfort preferences, and intended use.

References

Andersen, J. J. (2021, September 21). *The state of running 2019*. Athletic shoe reviews. Retrieved April 2022, from https://runrepeat.com/state-of-running

Arazpour, M., Bahramian, F., Abutorabi, A., Nourbakhsh, S. T., Alidousti, A., & Aslani, H. (2016). The effect of patellofemoral pain syndrome on gait parameters: A literature review. *Archives of Bone and Joint Surgery, 4*(4), 298–306.

Baker, R. L., Souza, R. B., Rauh, M. J., Fredericson, M., & Rosenthal, M. D. (2018). Differences in knee and hip adduction and hip muscle activation in runners with and without iliotibial band syndrome. *PM & R: The Journal of Injury, Function, and Rehabilitation, 10(*10), 1032–1039.

Baur, H., Divert, C., Hirschmüller, A., Müller, S., Belli, A., & Mayer, F. (2004). Analysis of gait differences in healthy runners and runners with chronic Achilles tendon complaints. *Isokinetics and Exercise Science, 12*(2), 111–116.

Braga, U. M., Mendonça, L. D., Mascarenhas, R. O., Alves, C. O. A., Filho, R. G. T., & Resende, R. A. (2019). Effects of medially wedged insoles on the biomechanics of the lower limbs of runners with excessive foot pronation and foot varus alignment. *Gait & Posture, 74,* 242–249.

Braunstein, B., Schulze, N., Sanno, M., & Bruggemann, G.-P. (2015). Comfort and plantar pressure pattern during running with prefabricated insoles. 33rd International Conference on Biomechanics in Sports, 536–539.

Chen, H., Nigg, B. M., & de Koning, J. (1994). Relationship between plantar pressure distribution under the foot and insole comfort. *Clinical Biomechanics (Bristol, Avon), 9*(6), 335–341.

Clement, D. B., Taunton, J. E., & Smart, G. W. (1984). Achilles tendinitis and peritendinitis: Etiology and treatment. The American Journal of Sports Medicine, 12(3), 179–184.

de Leva, P. (1996). Adjustments to Zatsiorsky-Seluyanov's segment inertia parameters. *Journal of Biomechanics. 29*(9), 1223-1230.

Dierks, T. A., Manal, K. T., Hamill, J., & Davis, I. (2011). Lower extremity kinematics in runners with patellofemoral pain during a prolonged run. *Medicine and Science in Sports and Exercise, 43*(4), 693–700.

Dixon, S. J. (2007). Influence of a commercially available orthotic device on rearfoot eversion and vertical ground reaction force when running in military footwear. *Military Medicine, 172*(4), 446–450.

Eng, J. J., & Pierrynowski, M. R. (1994). The effect of soft foot orthotics on three-dimensional lower-limb kinematics during walking and running. *Physical Therapy, 74*(9), 836–844.

Ferber, R., Davis, I. M., & Williams, D. S. (2003). Gender differences in lower extremity mechanics during running. *Clinical Biomechanics (Bristol, Avon), 18*(4), 350–357.

Fields, K. B. (2011). Running injuries - Changing trends and demographics. *Current Sports Medicine Reports, 10*(5), 299-303.

Gil-Calvo, M., Jimenez-Perez, I., Priego-Quesada, J. I., Lucas-Cuevas, Á. G., & Pérez-Soriano, P. (2020). Effect of custom-made and prefabricated foot orthoses on kinematic parameters during an intense prolonged run. *PLOS ONE, 15*(3), e0230877.

Hollander, K., Rahlf, A. L., Wilke, J., Edler, C., Steib, S., Junge, A., & Zech, A. (2021). Sex specific differences in running injuries: A systematic review with meta-analysis and meta-regression. *Sports Medicine (Auckland, N.z.), 51*(5), 1011–1039.

Johnson, C. D., Tenforde, A. S., Outerleys, J., Reilly, J., & Davis, I. S. (2020). Impact-related ground reaction forces are more strongly associated with some running injuries than others. *The American Journal of Sports Medicine*, *48*(12), 3072–3080.

Jordan, C., & Bartlett, R. (1995). Pressure distribution and perceived comfort in casual footwear. *Gait & Posture*, *3*(4), 215–220.

Kakouris, N., Yener, N., & Fong, D. T. P. (2021). A systematic review of running-related musculoskeletal injuries in runners. *Journal of Sport and Health Science, 10,* 513-522.

Landorf, K. B., Keenan, A.-M., & Herbert, R. D. (2006). Effectiveness of foot orthoses to treat plantar fasciitis: A randomized trial. *Archives of Internal Medicine, 166*(12), 1305–1310.

Lee, D.C., Brellenthin, A. G., Thompson, P. D., Sui, X., Lee, I.-M., & Lavie, C. J. (2017). Running as a key lifestyle medicine for longevity. *Progress in Cardiovascular Diseases, 60*(1), 45–55.

Lucas-Cuevas, A. G., Pérez-Soriano, P., Priego-Quesada, J. I., & Llana-Belloch, S. (2014b). Influence of foot orthosis customisation on perceived comfort during running. Ergonomics, 57(10), 1590–1596.

Majumdar, R., Laxton, P., Thuesen, A., Richards, B., Liu, A., Arán-Ais, F., Parreño, E. M., & Nester, C. J. (2013). Development and evaluation of prefabricated antipronation foot orthosis. *Journal of Rehabilitation Research and Development*, *50*(10), 1331–1342.

McKean, K. A., Manson, N. A., & Stanish, W. D. (2006). Musculoskeletal injury in the masters runners. *Clinical Journal of Sport Medicine*, *16*(2), 149–154.

Messier, S. P., Edwards, D. G., Martin, D. F., Lowery, R. B., Cannon, D. W., James, M. K., Curl, W. W., Read, H. M., & Hunter, D. M. (1995). Etiology of iliotibial band friction syndrome in distance runners. *Medicine and Science in Sports and Exercise*, *27*(7), 951–960.

Messier, S. P., Davis, S. E., Curl, W. W., Lowery, R. B., & Pack, R. J. (1991). Etiologic factors associated with patellofemoral pain in runners. *Medicine and Science in Sports and Exercise*, *23*(9), 1008–1015.

Milgrom, C., Radeva-Petrova, D. R., Finestone, A., Nyska, M., Mendelson, S., Benjuya, N., Simkin, A., & Burr, D. (2007). The effect of muscle fatigue on in vivo tibial strains. *Journal of Biomechanics*, *40*(4), 845–850.

Milner, C. E., Hamill, J., & Davis, I. S. (2010). Distinct hip and rearfoot kinematics in female runners with a history of tibial stress fracture. *Journal of Orthopaedic & Sports Physical Therapy*, *40*(2), 59–66.

Mündermann, A., Stefanyshyn, D. J., & Nigg, B. M. (2001). Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Medicine & Science in Sports & Exercise*, *33*(11), 1939–1945.

Mündermann, A., Nigg, B. M., Stefanyshyn, D. J., & Humble, R. N. (2002). Development of a reliable method to assess footwear comfort during running. *Gait & Posture*, *16*(1), 38–45.

Mündermann, A., Nigg, B. M., Humble, R. N., & Stefanyshyn, D. J. (2003). Foot orthotics affect lower extremity kinematics and kinetics during running. Clinical Biomechanics (Bristol, Avon), 18(3), 254–262.

Nawoczenski, D. A., Cook, T. M., & Saltzman, C. L. (1995). The effect of foot orthotics on three-dimensional kinematics of the leg and rearfoot during running. The Journal of Orthopaedic and Sports Physical Therapy, 21(6), 317–327.

Nigg, B. M., Nurse, M. A., & Stefanyshyn, D. J. (1999). Shoe inserts and orthotics for sport and physical activities. *Medicine & Science in Sports & Exercise, 31*(Supplement), S421–S428.

Nigg, B. M., Stergiou, P., Cole, G., Stefanyshyn, D., Mündermann, A., & Humble, N. (2003). Effect of shoe inserts on kinematics, center of pressure, and leg joint moments during running. *Medicine & Science in Sports & Exercise*, *35*(2), 314–319.

Noehren, B., Davis, I., & Hamill, J. (2007). ASB Clinical Biomechanics Award Winner 2006: Prospective study of the biomechanical factors associated with iliotibial band syndrome. *Clinical Biomechanics*, *22*(9), 951–956.

Noehren, B., Schmitz, A., Hempel, R., Westlake, C., & Black, W. (2014). Assessment of strength, flexibility, and running mechanics in men with iliotibial band syndrome. *The Journal of Orthopaedic and Sports Physical Therapy, 44*(3), 217–222.

Novick, A., & Kelley, D. L. (1990). Case study: position and movement changes of the foot with orthotic intervention during the loading response of gait. *Journal of Orthopaedic & Sports Physical Therapy*, *11*(7), 301–312.

Okunuki, T., Koshino, Y., Yamanaka, M., Tsutsumi, K., Igarashi, M., Samukawa, M., Saitoh, H., & Tohyama, H. (2019). Forefoot and hindfoot kinematics in subjects with medial tibial stress syndrome during walking and running. *Journal of Orthopaedic Research, 37*(4), 927–932.

Pohl, M. B., Mullineaux, D. R., Milner, C. E., Hamill, J., & Davis, I. S. (2008). Biomechanical predictors of retrospective tibial stress fractures in runners. *Journal of Biomechanics, 41*(6), 1160–1165.

Pohl, M. B., Hamill, J., & Davis, I. S. (2009). Biomechanical and anatomic factors associated with a history of plantar fasciitis in female runners. Clinical Journal of Sport Medicine: *Official Journal of the Canadian Academy of Sport Medicine*, *19*(5), 372–376.

Reinking, M. F., Austin, T. M., Richter, R. R., & Krieger, M. M. (2016). Medial Tibial Stress Syndrome in Active Individuals: A Systematic Review and Meta-analysis of Risk Factors. Sports Health, 9(3), 252–261.

Ribeiro, A. P., Trombini-Souza, F., Tessutti, V., Lima, F. R., de Camargo Neves Sacco, I., & João, S. M. A. (2011). Rearfoot alignment and medial longitudinal arch configurations of runners with symptoms and histories of plantar fasciitis. *Clinics*, *66*(6), 1027–1033.

Rice, H., & Patel, M. (2017). Manipulation of foot strike and footwear increases Achilles tendon loading during running. *The American Journal of Sports Medicine*, *45*(10), 2411 2417

.

Ring, K., & Otter, S. (2014). Clinical efficacy and cost-effectiveness of bespoke and prefabricated foot orthoses for plantar heel pain: A prospective cohort study. *Musculoskeletal Care*, *12*(1), 1–10.

Rodrigues, P., Chang, R., TenBroek, T., van Emmerik, R., & Hamill, J. (2015). Evaluating the coupling between foot pronation and tibial internal rotation continuously using vector coding. *Journal of Applied Biomechanics*, *31*(2), 88–94.

Scheerder, J., Breedveld, K., & Borgers, J. (2015). *Running across Europe: The rise and size of one of the largest sport markets*. Palgrave Macmillan.

Self, B. P., & Paine, D. (2001). Ankle biomechanics during four landing techniques. *Medicine and Science in Sports and Exercise, 33*(8), 1338–1344.

Sinclair J, Naemi R, Chockalingam N, Greenhalgh A. (2014). Investigation into the kinetics and kinematics during running in the heelless shoe. *Footwear Science, 6,* 1–7

Sinclair, J., Isherwood, J., & Taylor, P. J. (2015b). The effects of orthotic intervention on multisegment foot kinematics and plantar fascia strain in recreational runners. *Journal of Applied Biomechanics*, *31*(1), 28–34.

Sinclair, J., Richards, J. D., & Shore, H. (2016). Effects of semi-custom and off-the-shelf orthoses on Achilles tendon and patellofemoral kinetics in female runners. *Baltic Journal of Health and Physical Activity*, *8*(4), 7–15.

Smith, L. S., Clarke, T. E., Hamill, C. L., & Santopietro, F. (1986). The effects of soft and semi rigid orthoses upon rearfoot movement in running. *Journal of the American Podiatric Medical Association*, *76*(4), 227–233.

Stacoff, A., Reinschmidt, C., Nigg., B., Bogert, A., Lundberg, A., Denoth, J., Stussi, E. (2000). Effects of foot orthoses on skeletal motion during running. *Clinical Biomechanics, 15,* 54-64.

Taunton, J. E., Ryan, M. B., Clement, D. B., McKenzie, D. C., & Lloyd-Smith, D. R. (2002). Plantar fasciitis: A retrospective analysis of 267 cases. *Physical Therapy in Sport, 3*(2), 57–65.

van Gent, R. N., Siem, D., van Middelkoop, M., van Os, A. G., Bierma-Zeinstra, S. M., & Koes, B. W. (2007). Incidence and determinants of lower extremity running injuries in long distance runners: a systematic review. *British Journal of Sports Medicine, 41*(8), 469-480.

Wegener, C., Burns, J., & Penkala, S. (2008). Effect of neutral-cushioned running shoes on plantar pressure loading and comfort in athletes with cavus feet: A crossover randomized controlled trial. *The American Journal of Sports Medicine, 36*(11), 2139–2146.

Williams, D. S., McClay, I. S., & Hamill, J. (2001a). Arch structure and injury patterns in runners. *Clinical Biomechanics, 16*(4), 341–347.

Williams, D. S., McClay, I. S., Hamill, J., & Buchanan, T. S. (2001b). Lower extremity kinematic and kinetic differences in runners with high and low arches. *Journal of Applied Biomechanics, 17*(2), 153–163.

Willson, J. D., & Davis, I. S. (2008). Lower extremity mechanics of females with and without patellofemoral pain across activities with progressively greater task demands. *Clinical Biomechanics (Bristol, Avon), 23*(2), 203–211.

Yagi, S., Muneta, T., & Sekiya, I. (2013). Incidence and risk factors for medial tibial stress syndrome and tibial stress fracture in high school runners. Knee Surgery, Sports Traumatology, Arthroscopy, 21(3), 556–563.

Appendix. IRB Approval and Informed Consent

The following documents are the IRB approval and informed consent used for this study.

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office of Research Ethics
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 03/07/2022

To: Katie Bricarell Jason Gillette
From: Office of Research Ethics

Title: Biomechanical Analysis of Prescribed Prefabricated Insoles

IRB ID: 21-437
Submission Type: Initial Submission **Review Type**: Expedited

Approval Date: 03/07/2022 **Approval Expiration Date:** 03/06/2023

The project referenced above has received approval from the Institutional Review Board (IRB) at Iowa State University according to the dates shown above. Please refer to the IRB ID number shown above in all correspondence regarding this study.

To ensure compliance with federal regulations (45 CFR 46 & 21 CFR 56), please be sure to:

- **Use only the approved study materials** in your research, including the **recruitment materials and informed consent documents that have the IRB approval stamp**.

- **Retain signed informed consent documents for 3 years after the close of the study,** when documented consent is required**.**

- **Obtain IRB approval prior to implementing any changes** to the study or study materials.

- **Promptly inform the IRB of any addition of or change in federal funding for this study.** Approval of the protocol referenced above applies only to funding sources that are specifically identified in the corresponding IRB application.

- **Inform the IRB if the Principal Investigator and/or Supervising Investigator end their role or involvement with the project** with sufficient time to allow an alternate PI/Supervising Investigator to assume oversight responsibility. Projects must have an eligible PI to remain open.

- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.

- IRB approval means that you have met the requirements of federal regulations and ISU policies governing human subjects research. **Approval from other entities may also be needed.** For example, access to data from private records (e.g., student, medical, or employment records, etc.) that are protected by FERPA, HIPAA, or other confidentiality policies requires permission from the holders of

those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **IRB approval in no way implies or guarantees that permission from these other entities will be granted.**

- Your research study may be subject to **post-approval monitoring** **by Iowa State University's Office of Research Ethics**. In some cases, it may also be subject to formal audit or inspection by federal agencies and study sponsors.

- Upon completion of the project, transfer of IRB oversight to another IRB, or departure of the PI and/or Supervising Investigator, please initiate a Project Closure to officially close the project. For information on instances when a study may be closed, please refer to the IRB Study Closure Policy.

If your study requires continuing review, indicated by a specific Approval Expiration Date above, you should:

- **Stop all human subjects research activity if IRB approval lapses**, unless continuation is necessary to prevent harm to research participants. Human subjects research activity can resume once IRB approval is re-established.

- **Submit an application for Continuing Review** at least three to four weeks prior to the **Approval Expiration Date** as noted above to provide sufficient time for the IRB to review and approve continuation of the study. We will send a courtesy reminder as this date approaches.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.

ISU IRB: 21-437-00
Approved Date: 03/07/2022
Expiration Date: 03/06/2023

INFORMED CONSENT FORM

Title of Study: Biomechanical and comfort analysis on the use of commercial insoles while walking and running

Investigators: Katie Bricarell, Dr. Jason Gillette

Invitation to be Part of a Research Study

You are invited to participate in a research study. This form has information to help you decide whether or not you wish to participate - please review it carefully. Research studies include only people who choose to take part - your participation is completely voluntary and you can stop at any time.

Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Introduction and Purpose of the Study

The purpose of this study is to investigate how using commercially available prefabricated inserts affects biomechanics and injury mechanisms during running. Data from this study will be used to further knowledge about prevention of and rehabilitation from running related injuries.

Eligibility to Participate

You are being invited to participate in this study because you are 18 years of age or older and a healthy recreational or competitive runner that runs at least 10 miles per week. You should not participate if you have suffered a lower extremity injury in the past 3 months, have had surgery on a lower extremity in the past 12 months, or currently use orthotics.

Description of Study Procedures

Data collection will occur in two sessions and occur in the Biomechanics Lab, at 178N Forker Building, on Iowa State University's campus.

The first session will be for anthropometric measurements and initial evaluation of walking and running gait. You will be asked to review the informed consent document and given the opportunity to ask questions. You will also complete a Participant Questionnaire. You will wear your running shoes and running clothes to this session. Measurements of foot length, width, bending the foot up and down, bending the big toe up and down, and rotating the ankle outwards for joint range of motion will be taken using basic measuring devices such as a goniometer and measuring tape. Your height and weight will also be measured.

To collect video of normal gait, you will be asked to walk on the treadmill for 3 minutes. The first minute and a half will serve as a warmup where you may choose your preferred walking pace. During the second minute and a half, back and side view video recordings of your lower limbs will be taken. Video recordings will be used to evaluate foot position and movement during gait. These videos will not include any identifying information. You will be asked to repeat these steps for running. You will be asked to warm up and choose your preferred pace that is representative of your training pace during the first half, and video recordings of the lower limbs will be recorded during the second half of the 3 minutes. This session will take approximately 20-30 minutes. Videos will include your lower legs and feet only. If you have identifying marks like birthmarks or tattoos in these areas, they will be de-identified by covering them with athletic tape, made to be used on the skin, prior to viewing by a podiatrist. The podiatrist will use the walking and running videos to make a suggestion for the best match of three commercially available insoles for your foot type and movement. There will be no interaction between you and the podiatrist. Note that the podiatrist is not making these recommendations for medical purposes. Rather, he’s only making the recommendation as it relates to the study – to ensure the inserts used have the proper fit to achieve the aims of the research. Videos will be destroyed following the podiatrist’s recommendation.

The second session will serve as a more extensive biomechanical data collection. You will be asked to wear tight-fitting clothes, such as compression shorts or running shorts, and a tightfitting top or sleeveless shirt or jersey. If you do not have clothes that meet these criteria, the lab can provide them. You should wear the same shoes you wore for session 1. You will be asked to complete a warm-up consisting of a 5-minute jog. After the warm-up, 21 retroreflective markers will be placed on your dominant foot, dominant leg, pelvis, and trunk using disposable hypoallergenic marker adhesives to record 3D kinematics. Marker movement will be tracked by a 12-camera system in the lab. The camera records the marker movements only, not you, your body, or your face.

You will be asked to walk and run over force platforms embedded in the floor, a distance of approximately 30 feet for each trial. You will be asked to land your dominant foot on the first force platform and again on the second set of force platforms in the middle of the lab. The force platform records the forces produced during foot contact. There will be 5 footwear conditions that you will test for the walking trails. The walking conditions are barefoot, your regular shoe, insert 1, insert 2 and insert 3. You will walk through each condition 3 times at a preferred walking pace for a total of 15 walking trials. You will then complete running trials while wearing your regular shoes, insert 1, insert 2 and insert 3. You will complete three trials for each condition for a total of 12 trials at a pace representative of your normal training pace. You will not run in the barefoot condition. In total, 27 walking and running trials will be completed. The order of the walking and running trials will be balanced across participants. A separate, thin pressure insert will be used when wearing shoes to measure pressure on the bottom of your foot. You will be allowed time to practice and get comfortable with the equipment and movements before beginning data collection. You will complete a short comfort questionnaire at the end of data collection. Participation in the second session will last for approximately 60-75 minutes.

Expected Time or Duration of Participation:

The first session will take approximately 20-30 minutes. Your participation in the second session will last for approximately 60-75 minutes.

Risks or Discomforts

While participating in this study, you may experience the following risks or discomforts:
Any physical performance presents the risk of musculoskeletal injury. Situations of repetitive movement present the possibility of muscular soreness, or in extreme cases, injuries such as muscle, tendon, and ligament strains or ruptures.

To combat these possibilities, we will verify that you meet all inclusion/exclusion criteria. Only healthy, physically-active adults without a history of lower limb surgery will be included, which should minimize the chance of injury. If you identify any increases in pain, the session will be stopped and participation ended. A minimum of 30 seconds rest between trials should effectively combat fatigue (by allowing more than adequate time for muscular recovery), which could lead to overuse injury or soreness, and more rest is allowed.

Slight discomfort may occur as a result of unfamiliar inserts in your shoe. You will be provided an adjustment period to become more familiar with the feel and movement of the inserts. If you do not feel comfortable using the inserts, you may opt out at any time.

A same-sex researcher will be available to place markers on skin not covered by clothing. Participants will be asked if they prefer that the markers be placed by a same-sex researcher.

There may be risks or discomforts that are currently unforeseeable at this time. We will tell you about any significant new information we learn that may relate to your willingness to continue participating in this study.

Benefits to You and to Others

If you decide to participate in this study, there will be no direct benefit to you. It is hoped that the information gained in this study will benefit society by advancing our knowledge on how prefabricated inserts can be used to prevent running injuries.

Costs and Compensation

You will not have any costs from participating in this study. You will not be monetarily compensated for participating in this study. You can potentially receive extra credit (of no more than 0.5% the class grade) if enrolled in a Kinesiology class that offers such an opportunity. Kinesiology classes that do offer this option also offer alternative sources for extra credit. Please review your class syllabus and talk to your instructor. For example, sections of KIN 355 taught by Dr. Gillette offer multiple opportunities to obtain extra credit by participating in researchbased and non-research based data collections. Completing this Informed Consent document is considered participation. If the session is stopped for any reason, you are still entitled to extra credit.

Your Rights as a Research Participant

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences. You can skip any survey questions that you do not wish to answer. Your choice of whether or not to participate will have no impact on you as a student or employee in any way.

If you withdraw from the study early, all data collected up to the time of subject withdrawal must be retained in the trial database.

If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office of Research Ethics, Iowa State University, Ames, Iowa 50011.

Research Injury

Please tell the researchers if you believe you have any injuries caused by your participation in the study. The researchers may be able to assist you with locating emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. Eligible Iowa State University students may obtain treatment from the Thielen Student Health Center. By agreeing to participate in the study, you do not give up your right to seek payment if you are harmed as a result of being in this study. However, claims for payment sought from the University will only be paid to the extent permitted by Iowa law, including the Iowa Tort Claims Act (Iowa Code Chapter 669).

Confidentiality

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies, the Food and Drug Administration, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy study records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken: Any data recorded about you will be dissociated from your identity through a numeric key. The data will be secured in locked filing cabinets in a locked office on campus. Digital data will be stored on password-protected computer. These data can be only identified by participant number. The key linking your participant number to your identity will be stored away from your data and will be destroyed once data collection is complete.

When the data from this study are eventually presented, no information derived from the data will indicate your identity.

Future Use of Your Information

De-identified information collected about you during this study may be shared with other researchers or used for future research studies. These studies may be similar to this study or completely different. We will make sure that your identity cannot be linked to the information we share. We will not obtain additional informed consent from you before sharing the deidentified data.

Questions

You are encouraged to ask questions at any time during this study. For further information about the study, contact Katie Bricarell at bricarek@iastate.edu or Dr. Jason Gillette at gillette@iastate.edu or (515) 294-8310.

Your Consent

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document, and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your participation in the study.

I certify that I am 18 years of age or over (Yes/No)

Participant's Name (printed): ____

Participant's Signature _____________________________________ Date: ____________

CHAPTER 4. GENERAL CONCLUSIONS

In a combined evaluation of kinematic, kinetic, plantar pressure, and comfort score data, there was a mix of potential benefits, drawbacks, and perceptions of insole use. The Currex insole reduced ankle eversion and peak midfoot pressure during walking, while reducing peak toe and average whole foot pressure during running. The PowerStep insole also reduced ankle eversion and peak midfoot pressure during walking, while reducing Achilles tendon load and ankle inversion moment during running. Increased average midfoot pressure is potentially a measure for decreased perceptions of comfort. Increased average midfoot pressure for the PowerStep insole may be linked to decreased comfort scores. As expected, the softer and more flexible Currex insole was preferred over the more rigid PowerStep insole. However, no comfort score improvements were observed between the Currex insole and regular shoe condition. These conflicting results may indicate that prefabricated insoles are only potentially beneficial when matched to an individual's biomechanical needs, comfort preferences, and intended use.

Further studies involving a large prospective participant pool and dividing participants by more individualized characteristics such as arch type and foot strike pattern are needed. Such studies may provide further understand of potential associations between biomechanical variables and perceptions of comfort. Each participant in this study used the same model of insoles regardless of foot type or gait patterns. Because the optimal choice of insole likely requires an individualized approach, it's possible that the insoles used in this study did not meet the functional needs of each participant. In addition, the current study only measured acute effects of insole use. Future studies could focus on longer duration and/or long-term effects of fatigue and more gradual adjustments of kinematic patterns, kinetic patterns, and comfort perceptions of insole use. Finally, the current study involved only healthy runners. Future studies could prospectively follow runners to observe any links between individual characteristics, insole use, and those who develop running related injuries and those who do not.

Appendix. Recruitment Email, Participant Questionnaire, Comfort Questionnaire

The following documents are the participant questionnaire, and comfort questionnaire signed and completed by participants as well as the recruitment email used for this study.

Email:

Hello,

The ISU Biomechanics Lab is looking for volunteers to help analyze the effects of prefabricated inserts in runners.

Come experience biomechanics research as you walk and run under different footwear conditions. Testing will be two sessions. The first being approximately 20-30 minutes, and the second approximately 60-75 minutes. Participants will wear running clothes and shoes to both visits.

Data collection will use motion tracking to measure your movements as well as force platforms and pressure sensors to measure loads applied to the plantar surface of your feet. Videos will be used to assign the appropriate inserts.

Volunteers must be 18 years of age or older and run at least an average of 10 miles per week. You should not participate if you have suffered a lower extremity injury in the past 3 months or have had surgery on a lower extremity in the past 12 months.

Interested? Contact Katie Bricarell (bricarek@iastate.edu) for more information.

Thanks!

Katie Bricarell

Participant Questionnaire

Participant Number:

To be completed by the Participant:

Personal Information

Age:

Sex:

Body Mass:

Height:

Weekly Mileage:

Years Running:

Type of Runner: Recreational Competitive

Shoe Size:

Lower extremity injury/surgery history:

To be completed by the Researcher:

Foot Length:

Foot Width:

Ankle ROM:

Sub-Talar ROM:

First Metatarsophalangeal ROM:

Comfort Questionnaire

Please rate comfort using the following scale:

	1	**2**	**3**	**4**	**5**
	Uncomfortable				**Comfortable**

Running Shoe Comfort:

Forefoot	1	2	3	4	5
Midfoot	1	2	3	4	5
Rearfoot	1	2	3	4	5

Insert 1 Comfort:

Forefoot	1	2	3	4	5
Midfoot	1	2	3	4	5
Rearfoot	1	2	3	4	5

Insert 2 Comfort:

Forefoot	1	2	3	4	5
Midfoot	1	2	3	4	5
Rearfoot	1	2	3	4	5

Which condition was more comfortable?

Running Shoe Only	Insert 1	Insert 2	No Preference

Why?