THE PENNSYLVANIA STATE UNIVERSITY
SCHREYER HONORS COLLEGE

DIVISION OF SCIENCE

THE EFFECT OF VARIOUS MILITARY ISSUED FOOTWEAR ON IMPACT LOADING
DURING RUNNING

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SPRING 2020

A thesis
submitted in partial fulfillment
of the requirements
for a baccalaureate degree
in Kinesiology
with honors in Kinesiology

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ABSTRACT

Military members have a high musculoskeletal injury rate, which limits physical participation. These injuries are due to overuse and may be caused by repeated impact loading to the lower extremities. These issues usually start in boot camp and occur more often in women. The purpose of this study was to assess the impact-related injury risk of three types of military footwear during running. It was expected that impact loading would be higher in the stiff boots compared to the running sneakers. Ground reaction forces were collected for 15 female test subjects in their personal running shoes and two different military issued combat boots. The impact peak (IPz), average loading rate (ALRz), instantaneous loading rate (ILRz), and peak force (Peakz) were extracted from the vertical ground reaction force and compared among the three types of footwear using one-way repeated measures ANOVA. Instantaneous load rate for the sneaker was 25.5% greater than the Belleville (Bell) boot and 34.5% greater than the OCP tactical (OCP) boot. Average load rate for the sneaker was 51.8% greater than the Bell boot and the Bell boot was 48.0% greater than the OCP Boot. The sneaker was 29.0% more comfortable compared to the OCP boot and 64.3% more comfortable compared to the Bell boot. Impact peak and peak force were not different between the footwear conditions. This data shows, contrary to the hypothesis, that impact is absorbed better in combat boots compared to sneakers because of the sole thickness. These findings do match previous studies, that there was an inverse change between impact loading and hardness of the sole. The data suggests that high impact loading in combat boots does not contribute to high rates of injury in military service members. The high rate of injury may be explained by other factors such as the muscular demand due to the weight of the boot, kinematic factors, or training factors.
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Completing this thesis would not have been possible without my military experience and the support from my professors and family along the way.

Throughout my time in the military, I was one of the many that suffered from overuse injuries. Everyone I served with thought that a majority of the injuries were from the combat boots we wore every day. This experience inspired me to investigate if there was a correlation between these injuries and impact loading. My curiosity will hopefully lead to further research to determine if there is a way to reduce the number of injuries our service members acquire during their service.

The first person I would like to thank is Dr. Allison Altman-Singles. Without her guidance, I would not have narrowed down my idea for my thesis. Dr. Singles helped me develop writing to reflect proper research writing techniques. She not only guided me through my thesis, but my entire undergraduate degree. Throughout this time, she also helped me to recognize my potential. It is because of her that I involved myself in research early on and became an honors student. I thank her for all her guidance and for enhancing my education more then I personally would have achieved alone.

I would also like to thank Dr. Sandy Feinstein. Dr. Feinstein helped me throughout the entire writing process of my thesis. I appreciate all of the time she invested editing and providing me with feedback which allowed me to create the best final product I could. I thank her for her devotion to not only my thesis but also to myself and for all of the guidance she has provided along the way.
Finally, I would like to thank my friends and family who have supported me along the way, not only with my thesis but throughout my collegiate career at Penn State Berks. My friends and family have always been there for me, from my time in the military to the transition into civilian life and college. Especially my mom, who has been my anchor through anything in life I pursue.
Chapter 1

Introduction

Physical participation is crucial for military service members. Unfortunately, military members have very high musculoskeletal injury rates, which inhibits physical participation in marching, running and being mission ready. Male recruits experience 10-15 lower extremity injuries per 100 male recruits, and female recruits experience 15-25 injuries per 100 female recruits (Kaufman & Shaffer, 2000). Many of these musculoskeletal injuries are due to overuse caused by repeated stress to the lower extremities. Overuse injuries cause tendinitis, stress fractures, lower back pain, muscle sprains/strains, iliotibial band syndrome, knee and ankle injuries (Kaufman & Shaffer, 2000). Multiple factors contribute to overuse injuries, and these factors may be physiological, environmental or biomechanical. These injuries vary depending on the type of training. The main concern to the military is the frequency of injuries and time lost from training. An injury such as a stress fracture can delay recruit training by 6-8 weeks (Milgram & Finestone, 2017). The military loses approximately $31,000 per recruit lost due to injury (Sisk, 2018). These issues usually start in boot camp because military members have to achieve and maintain mission readiness status which requires intense training.

Stress is produced when the foot strikes the ground and the force causes tension, compression, shearing, torsion and bending to the lower extremities (Cohen, 2017). Compression from impact loading may cause bending moments as the projection of vertical vector forces travel through the lower extremities (Milner et. al., 2006). The high impact loading increases the risk of stress fractures (Pohl, 2009). Stress fractures are a typical overuse injury that accounts for
50% of the injuries recruits suffer from in the military (Milner et. al., 2006). Stress fractures are structural micro-damage to the bones and are common to the lower extremity of the musculoskeletal system. These fractures occur in areas with biological structures where the bone may or may not have the ability to repair the damage (Milgram & Finestone, 2017). Stress fractures can be minor and have a quick recovery as long as they stay in the micro stage but can enter the macro stage if not appropriately treated. Treatment for stress fractures starts with two weeks of rest and if the symptoms are eliminated, then the fractures are labeled as clinical stress fractures (Milgrom & Finestone, 2017). If the symptoms reoccur, x-rays need to be taken and activity needs to be restricted for two to eight weeks depending on the severity (Milgrom & Finestone, 2017). It is important to encourage recruits to not hide any type of pain they may have. The longer a recruit waits to get a diagnosis, the longer the recovery period.

Common areas that develop stress fractures are the tibias, metatarsals, and femurs, caused by repetitive and excessive loading of the lower extremities (Milgrom & Finestone, 2017). Assessments to determine stress fractures in the tibia consist of localized pain when jumping on one leg and tenderness during palpation of the localized area (Milgrom & Finestone, 2017). The metatarsal assessment involves deep palpation of the dorsal aspect of the foot (Milgrom & Finestone, 2017). A bone scan can be used after the diagnosis to determine the severity of the stress fracture (Milgram & Finestone, 2017). These types of stress fractures have multiple causes such as high free moments (the torque about the vertical axis where the foot contacts the ground) and high impact loading (how hard the foot contacts the ground during walking and running) (Jacob et. al., 2014). Some demographic risk factors include the recruits’ fitness level before bootcamp, gender, age and anatomical factors (Jones & Knapik, 1999).
The fitness level of the recruits before entering boot camp is a risk factor to consider. Essential components of fitness include cardiorespiratory endurance, muscle strength and endurance, along with flexibility and body composition (Jones & Knapik, 1999). These components of fitness are tested during the military physical fitness tests, including one and a half to three-mile runs, push-ups, sit-ups and in some branches pull-ups. Boot camp is designed to make recruits into mission-ready military members in a two to three-month training regimen. Training consists of a combination or high volumes of running, marching, calisthenics, climbing, hurdling crawling, jumping, lifting, and carrying heavy loads (Jones & Knapik, 1999). In boot camp, there is no gradual increase in exercises to prepare for the physical fitness test. Going from a sedentary lifestyle to a highly active lifestyle in boot camp, without a gradual increase, adds stress to the lower extremities (Jones & Knapik, 1999). The lower extremities succumb to excess loading and add stress to muscles, ligaments, tendons and bone causing injuries (Jones & Knapik, 1999).

Gender has been shown to be a risk factor in the injury rate of military members. Females are 1.5 – 2 times more likely to obtain musculoskeletal injuries over males (Jones & Knapik, 1999). Anatomical structural differences between males and females have been theorized to be a part of how their running mechanics may differ (Ferber et. al., 2003). Because women can bear children, their hips are wider compared to men and have more elasticity in their ligaments to accommodate childbirth. Wider set hips change the angle of lower extremities. The wider hip frame to femoral length ratio in females leads to greater hip adduction, internal rotation, knee abduction, but decreases internal rotation of their knees compared to males (Ferber et. al., 2003). A greater static genu valgus that has been reported in women is from the increased angulation of the femur (Ferber et. al., 2003). These different structures in females may contribute to different
movement patterns, putting them at a greater risk for stress fractures and lower extremities injuries to the knees and hips in correlation to running and walking mechanics compared to that of males (Miler et. al., 2006).

As was mentioned previously, another risk factor for injuries to military members is high impact loading. When the foot comes in contact with the ground, there is a force exerted on the body. The force is transmitted through the bones and soft tissue of the lower extremities. This force is called the ground reaction force from impact loading and can be measured by running or walking across a force plate. The foot strike during running can be measured by a force plate to assess where the center of pressure is initially located (Mercer & Horsch, 2015). There are three types of foot strikes, the rear foot (heel-toe), mid foot and fore foot (Mercer & Horsch, 2015). Rearfoot striking, which is most common in military recruits, is associated with the highest impact loading (Mercer & Horsch, 2015). As the impact forces travel through the body, the body is required to adapt to prevent injuries (Khan et. al., 2018). The impact loading on the body can range between 2.5-2.8 times an individual’s body weight (Milner et. al., 2006). When the lower extremities fail to adapt to the loading mechanics, injuries occur (Khan et. al., 2018). This failure to adapt prevents the osteoclasts from remodeling the bone, leading to fractures (Khan et. al., 2018). Impact loading has been linked to injury because damage is done to the bones from the repetitive nature of the force exerted on the body at impact (Khan et. al., 2018). Impact loading can be influenced by loading rates, footwear and anatomical elements.

Structural alignment and movement biomechanics during physical activity can be influenced by footwear. Different footwear can affect the force exerted on the body during gait by restricting foot movement, along with how the foot contacts the ground. Footwear can alter the stride length, running cadence and the surface of the ground which would influence the
impact forces during loading (Mercer & Horsch, 2015). These changes may further compound overuse injury occurrence in military recruits who are required to wear various different footwear for different activities. Continuous excess loading in different footwear increases the stress on the lower extremities musculoskeletal system causing injuries (Jones & Knapik, 1999).

Combat boots play a specific role for military members. The type of combat boot worn in the military depends on the military branch and job. Each branch has its own requirement for uniform standards and job performance, but all combat boots have the same basic structure to allow for protection and support. Two types of combat boots utilized by the military in the desert are Belleville 390DES hot weather combat (Bell) boot (Figures 1 & 2) and OCP tactical (OCP) boot (Figures 3 & 4). These boots were designed with a thick sole to protect the foot from trauma such as high impact loading from explosives and ankle support (Muniz & Bini, 2017).
Figure 2. Belleville Combat Boot Side View

Figure 3. OCP Combat Boot Front View
Thick soles provide protection from foreign objects that can penetrate the foot as well as from IED’s (improvised explosive devices) (Newel et. al., 2011). IED’s can completely destroy the foot inside the boot while the boot stays completely intact (Newel et. al., 2011). The thick sole offers protection but adds excess weight and no cushioning for shock absorption (Newel et. al., 2011). Heavier shoes change the walking gait by increasing the stride length, causing a higher energy expenditure and potentially increasing impact loading (Knapik et. al., 2015). The altered gait affects the lower extremity muscle activation which attenuates shock absorption from impact loading (Muniz & Bini, 2017).

The high ankle structure of the combat boot provides support to protect the foot and ankle from sprains and strains. However, the boot’s design to support restricts motion and causes other complications. Motion is restricted across the malleoli and stresses the ventral muscles, leading to injuries such as shin splints (Muniz 2017). Shin splints, when left untreated, can lead to stress fractures (Milgrom & Finestone 2017).

In the past, boots were the only form of footwear recruits used during training. All recruits were required to perform their fitness test and fitness training in combat boots. An army
commander changed the rule to allow running shoes to be used for fitness testing and training (Knapik et. al., 2015). The injury rates of recruits continued to increase which resulted in training time lost. The thought was to reduce the frequency of injuries to the musculoskeletal system (Knapik et. al., 2015). An injury analysis suggests that the occurrence of injuries in each footwear type was different (Knapik et. al., 2015). The structure of each footwear was thought to hinder the lower extremities proper range of motion and alter the foot's mechanics. Any change in the body’s mechanics prevents the body from naturally responding to impact loading. Combat boots are a good example of how structure may contribute to injury risk because of the added weight and stiffness when running. However, because of the long-term nature of overuse injuries, the cumulative effects of the boots may increase injury risk (Knapik et. al., 2015).

The purpose of this study is to assess injury risk through impact loading with three types of military issued footwear during running. Three different footwear conditions were analyzed on female test subjects to assess ground reaction forces because females have a higher risk of injury to their lower extremities (Ferber et. al., 2003). The test subjects wore their personal training shoes and then two different combat boots that are currently being utilized by the military forces in the desert. The hypothesis was that personal training shoes would provide maximal protection from impact loading compared to the two types of combat boots tested. By assessing the loading on the lower extremities from the ground reaction force, injuries can be mitigated by changing the footwear used by the military or increasing the time recruits spend in footwear associated with reduced injury risk (Muniz & Bini 2017).
Chapter 2

Methods

Recruitment

Participants were recruited for this study with approval from Penn State University’s internal review board (IRB Appendix A). A recruitment speech (Appendix B) was used to elicit interest from various groups, including friends, classmates, and those currently in service to the military. In addition, recruitment flyers (Appendix C) were handed out at local facilities such as Penn State Berks campus, gyms and recreation facilities. In this manner, a sample of convenience was used. 15 participants expressed interest (7 from word of mouth and 8 from flyers). All of those who expressed interest in participating were queried regarding the inclusion criteria detailed in the following section.

Participants

As mentioned previously, all participants had to meet the inclusion criteria before they could participate in the study. Of the 18 people who expressed interest in the study, 15 met the inclusion criteria. The inclusion criteria were verified using a set of screening questions (Appendix D). These questions confirmed that the participants were female and between the age of 18-30 years old. The females could not be pregnant to participate. These females had no musculoskeletal injuries to the lower extremities and no cardiovascular or physical limitations. Each participant ran a minimum of three miles a month. All participants self-identified themselves as healthy individuals that maintain a physically active lifestyle. The participants also had to fit in the combat boots provided (size 6 or 7). All participants ran in boots and were comfortable running across a seven-meter runway several times. Men were excluded from this
study as the injury mechanics in military recruits differ dramatically by gender, and females are particularly affected by high impact loading (Kaufman 2000).

Once a participant was determined to have met the inclusion criteria, they were scheduled for participation. A consent form (Appendix E) was discussed with each test subject and signed stating they understood the requirements and procedures of the study. After consent, each participants’ height was measured.

**Procedure**

In order to collect data, the force plate (Bertec, Columbus, OH, USA) had to be zeroed. Then the participants put on their personal running shoes and stood on the force plate to record their weight. After measuring weight, each participant warmed up by jogging in her personal running shoes down the seven-meter runway. Once warmed up, participants began running over the force plate for data collection. Adjustments were made to the starting position of the participants to ensure that the plate was being struck with the dominant foot. The participant either had to start closer to the force plate or farther away to ensure that their dominate foot landed on the force plate without having to change their running stride. Five satisfactory trials were collected in their personal running shoes. A satisfactory trial was defined as one where the dominant foot lands centered on the force plate. The complete stance phase was captured using the Vicon Nexus Software (Vicon, Denver, CO, USA). Data was recorded at a frame rate of 1000 Hz.

The combat boot testing order was selected at random between the Belleville 390DES hot weather combat boot and the military uniform supply OCP tactical boot. Up to ten minutes was provided to each participant to warm up and adjust to the weight of each combat boot by jogging
down the seven-meter runway. Once the participants felt that they were warmed up running in the boot, five satisfactory running trials of the dominant foot striking the force plate were collected. The comfort of the combat boot was gathered from each test subject using a comfort scale, where 1 indicated not being comfortable and 5 indicated being very comfortable (Appendix F). The second combat boot was collected in the same manner.

To calculate the variables of interest, the data from the Nexus software were transferred to the MATLAB (Natick, MA. USA) software. The Visual 3D software calculated the parameters of interest from the ground reaction force curve (Figure 5). Force parameters were normalized by body weight. Vertical loading rate is the slope of the line from initial foot contact to full foot contact with the ground. Both the instantaneous (highest) and average (mean) loading rate were extracted from the slope. Impact peak is the first peak where the whole foot is in contact with the ground. Propulsive peak is the highest peak where the foot is pushing off from the ground.

![Vertical Ground Reaction Force Curve](image)

*Figure 5. Vertical Ground Reaction Force Curve*
Statistics

The mean impact peak (IPz), propulsive peak (Peakz), average loading rate (ALRz) and instantaneous loading rate (ILRz) were calculated for each condition, personal trainers, combat boot 1 and combat boot 2. The parameters were compared in SPSS using one-way repeated measures ANOVA. If the p-value was less than 0.05, then there was a significant difference between the conditions. Post hoc t-tests were used to determined which conditions were driving significant ANOVA results. Comfort levels were compared using pared t-tests between boot conditions.
Chapter 3 Results

Subjects

Fifteen female subjects were recruited from Penn State Berks campus, gyms and recreation areas. Characteristics of the test subjects are shown below (Table 1). Out of fifteen test subjects, only one had military experience.

Table 1. Test Subject Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Means ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (female)</td>
<td>15</td>
</tr>
<tr>
<td>Age (years)</td>
<td>25.6 ± 3.40</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.67 ± 0.06</td>
</tr>
<tr>
<td>Weight (N)</td>
<td>685.3 ± 81.9</td>
</tr>
</tbody>
</table>

Impact Peak

There was no significant difference (p-value = 0.739) in the mean impact peak between the sneaker, Bell combat boot and the OCP combat boot (Figure 6).

Figure 6. Impact Peak Among Footwear
Instantaneous Loading Rate

There was a significant difference (p-value = 0.013) in the mean instantaneous loading rate between the sneakers, Bell combat boot and the OCP combat boot (Figure 7). The sneaker had the highest instantaneous loading rates, followed by the OCP combat boot which was 25.5% less than the sneakers (p-value = 0.034), then the Bell combat boot that was 34.5% less than the sneaker (p-value = 0.015). When comparing the boots to each other, there was no difference indicated (p-value = 0.445).

Figure 7. Instantaneous Loading Rate Among Footwear

Average Loading Rate

There was a significant difference (p-value = 0.000) between the mean average loading rates of the sneaker, Bell combat boot, and OCP combat boot (Figure 8). The sneaker had the highest average loading rate, followed by the OCP combat boot (p-value = 0.484), then Bell combat boot with 51.8% less than the sneakers (p-value = 0.000). The boots were compared to
each other, and the Bell combat boot was 48.0% less than the OCP combat boot (p-value = 0.000).

![Figure 8. Average Loading Rate Among Footwear](image)

**Peak Force**

There was no significant difference (p-value = 0.074) in the mean peak force of the sneaker, Bell combat boot, and OCP combat boot (Figure 9). The p-value was trending toward significant. The OCP combat boot had the highest peak impact, followed by the Bell combat boot, then the sneaker. There was a significant difference (p-value = 0.026) between the sneaker and the OCP combat boot. The OCP combat boot was 2.17% less than the sneaker. The Bell combat boot was 1.63% less than the OCP combat boot which was trending towards being significant (p-value = 0.060). No differences were found when the sneaker was compared to the Bell combat boot (p-value = 0.644).
Figure 9. Peak Force Among Footwear

**Comfort**

There was a significant difference (p-value = 0.000) between the mean comfort levels of the sneakers, Bell combat boot and OCP combat boot (Figure 10). The comfort of the sneaker was the highest, followed by the OCP combat boot which was 29.0% less than the sneaker (p-value = 0.000), then the Bell combat boot that was 64.3% less than the sneaker (p-value = 0.000). When the mean values of the combat boots were compared to each other, there was significant difference (p-value = 0.000). The OCP combat boot had a higher comfort level compared to the Bell combat boot which was 36.9% lower.
Figure 10. Comfort Level Among Footwear
Chapter 4

Discussion and Conclusion

The hypothesis that sneakers would have a greater ability at absorbing impact loading compared to combat boots was not supported by this study. It seems that the combat boot itself is better for shock absorption purposes than sneakers. The data show that it is better to run in combat boots because the soles are thicker and structured differently to absorb more impact loading compared to normal running shoes. The greatest difference between the types of footwear was the instantaneous and average load rates. The Bell combat boot showed the lowest loading rate followed by the OCP combat boot and, lastly, the sneaker, suggesting that there is a strong correlation between the sole thickness and shock absorption properties.

Despite the relationship between loading rates and impact peak, no differences were found between the impact peak of the different types of footwear, which was likely caused by the high variation between footwear conditions. The high variability in the impact peak can be explained by the inconsistent foot strike patterns between the runners and different footwear conditions. In a rear foot strike, high impact peaks are correlated with high loading rates (Milner et. al., 2006), but when a runner strikes the ground with the ball of the foot first, impact peak is sometimes not present and may not be correlated with loading rates. The peak force, while not related to injury rates, showed a potential trend toward a higher peak force in combat boots. It is possible that as the weight of the footwear increases, a higher push off force is required.

Stress fractures are a common injury to the lower extremities of service members (Milner et. al., 2006). The hypothesis of this paper was based on the theory that stress fractures in service members are likely a result of repetitive excess loading while wearing combat boots. This study does not support this theory because the Bell combat boots reduced impact loading
the most followed by the OCP combat boots and the sneakers absorb the least amount of shock when running. These findings matched previous data that analyzed ground reaction forces to assess impact loading. Previous findings discovered that there was an inverse relationship between impact loading and the hardness of the sole (Muniz & Bini, 2017). If the impact loading is reduced by increasing the sole thickness, then the boots are better at minimizing shock compared to sneakers. Since injury rates in service members remain high, it is possible that other factors related to the boots are increasing the rate of injury.

The results found in this study demonstrate the complexity that a thick boot sole adds to the analysis of impact loading. The boot sole may have altered the amount of loading passed on to the runner more than a typical running shoe, so it is possible that testing with shoe inserts would reveal additional insight. The thickness of the sole allows for the ability to absorb impact loading through elastic deformation, but it also adds weight and discomfort to the combat boots. Sneakers weigh about 0.269 kg, while the Bell combat boots weigh 2.04 kg and the OCP boots weigh 0.953 kg. The Bell combat boots weighed the most and were rated the least comfortable compared to the OCP combat boots and the sneakers. Previous research has shown that biomechanical adaptations occurred when participants ran with added weight (Lobb et. al., 2019). These adaptations involve stiffening of the lower extremities to prevent the body from collapsing under the added weight (Lobb et. al., 2019). If the combat boots absorb a majority of the impact but add weight, it is possible that a biomechanical adaptation occurs because of the weight of the combat boots which require an increased muscular demand.

One key limitation for this study was the participants’ lack of military experience. The lack of military experience prevented the test subjects from having experience running in combat boots which could have led to a higher variability in impact loading. Combat boots are structured
differently from sneakers because they serve a different purpose compared to the sneaker. Boots limit the mobility of the ankle and add weight to the lower extremities. In this study, mobility was especially limited due to the high stiffness of the brand-new boots used. The rigidness of the footwear stresses the lower extremities differently from sneakers (Muniz 2017). Being unaccustomed to the weight or stiffness could alter the way these test subjects ran across the force plate. Poor mobility of the ankle hinders the lower extremities from functioning properly during a normal gait cycle. If the joint motion is interrupted, then the lower extremities compensate for the limited mobility, increasing stress on the muscles during running (Muniz 2017). Stride length may have been altered by the weight of the boots and limited ankle mobility, which could have influenced the runners speed across the force plate. Having a controlled speed in this study by setting a pace for each runner could have eliminated some of the variation observed within and among participants.

The collection of additional data in future studies could help reveal additional risk factors for injury that were not hypothesized in this study. Motion analysis could be used to collect kinematic data, such as joint angles and segmental motion, which would allow for wider conclusions to be drawn regarding kinematic mechanisms for shock absorption and altered stride lengths from leg stiffness. Combat boots create a heavier pendulum on the lower extremities during a normal gait cycle because the flexor muscles could be contracting more which would shorten the stride. Shorter strides may be the reason impact loading was reduced. Kinematic data could also allow for the calculation of joint forces and moments that would reveal how impact loading is absorbed by the body. In addition, repeating the test with a pressure insole to the shoe could potentially provide insight into how much impact load is dissipated by the sole of the boot and how much is transferred to the runner.
A bigger sample size with an equal population of service members and civilians could allow for a more thorough study. Service members wear combat boots every day, and the continuous uses over time lets the boots function like normal shoes. Therefore, military service members are more experienced in combat boots and may display different compensation mechanisms compared to civilians. Using both military service members and civilians could also allow for a comparison on how the body adapts to combat boots. Increasing the number of subjects could also allow for increasing statistical validity to observe differences in all variables, rather than just the loading rates.

This study could also be extended over a longer period of time to allow the test subjects to adapt to running in combat boots. Increasing the duration of the study could offer more time for the boots to break in properly for the test subjects and a chance for the boots to change with the environment. This study did not assess how the combat boots change with temperature, moisture, shearing forces and static compression that would actually occur during the service members’ daily function (House et. al., 2002). Extending the study could allow for a better understanding of how impact loading changes over time. As the boots are broken in, the sole starts to deteriorate which lowers the shock absorption properties (House et. al., 2002). Knowing the deterioration rate would help to pinpoint when exactly combat boots need to be replaced, which could also prevent excess impact loading.

Future studies could also look at a variety of different combat boots. Every branch uses multiple different combat boots. The type and style of the combat boot service members are issued depends on the area where they are stationed. These boots not only differ aesthetically, they vary in the material used to make them. Some boots are made from different kinds of leather and others are made from cloth, which could also alter their stiffness and overall
structure. The soles also differ in thickness, which could impact the shock absorption process for which they were designed. Looking at a variety of combat boots would provide a broader understanding of how impact loading changes across different combat boots. Understanding the difference in shock absorption properties could determine the type of combat boots the troops should wear to prevent injuries.

Anecdotal evidence from military service members suggested that injuries may have been caused by combat boots, but the source of these injuries has yet to be scientifically proven. This study is the first step toward identifying a relationship between combat boots and overuse injuries. Findings from this study have determined that combat boots have a better shock absorption compacity over sneakers. This study concludes that high impact loading in combat boots does not contribute to high rates of injury in military service members. The high rate of injury may be explained by other factors such as the muscular demand impacted by the weight of the boot, kinematic factors, or training factors. Further studies need to be done to assess what is the main cause behind why service members have a high injury rate to their lower extremities. It is important to understand the exact cause of these injuries so that they can be prevented.
Appendix A

Protocol

HRP-591 - Protocol for Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS IRB (http://irb.psu.edu).

The Effect of Various Military Issued Footwear on Impact Loading During Running

Principal Investigator:
Name: Allison Singles
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E-mail Address: ara5093@psu.edu

Version Date:

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

October 25, 2019

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See “HRP-103- Investigator Manual, When do I have to register my project at ClinicalTrials.gov?” for more information.

na
Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. GENERAL INSTRUCTIONS:
   • Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   • Do not change the protocol template version date located in the footer of this document.
   • Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   • GRAY INSTRUCTIONAL BOXES:
     o Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     o Penn State College of Medicine/Penn State Health researchers: Delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (http://irb.psu.edu).
     o Penn State researchers at all other campuses: Do NOT delete the instructional boxes from the final version of the protocol.
   • Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the “Basic Information” page.

2. CATS IRB LIBRARY:
   • Documents referenced in this protocol template (e.g. SOP’s, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. PROTOCOL REVISIONS:
   • When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
   • Update the Version Date on page 1 each time revisions are made.

If you need help...

<table>
<thead>
<tr>
<th>University Park and other campuses:</th>
<th>College of Medicine and Penn State Health:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Office for Research Protections Human Research Protection Program</strong></td>
<td><strong>Human Subjects Protection Office</strong></td>
</tr>
<tr>
<td>The 330 Building, Suite 205</td>
<td>90 Hope Drive, Mail Code A115, P.O. Box 855</td>
</tr>
<tr>
<td>University Park, PA 16802-7014</td>
<td>Hershey, PA 17033</td>
</tr>
<tr>
<td>Phone: 814-865-1775</td>
<td>(Physical Office Location: Academic Support Building Room 1140)</td>
</tr>
<tr>
<td>Fax: 814-863-8699</td>
<td>Phone: 717-531-5687</td>
</tr>
<tr>
<td>Email: <a href="mailto:irb-orp@psu.edu">irb-orp@psu.edu</a></td>
<td>Email: <a href="mailto:irb-hspo@psu.edu">irb-hspo@psu.edu</a></td>
</tr>
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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

The purpose of this study is to assess injury risk through impact loading with three types of military issued footwear during running. The objective is to analyze female test subjects ground reaction force as they run across force plates. These test subjects will be wearing their personal running sneakers to achieve a baseline ground reaction force, then run across the force plate with Belleville 390DES hot weather combat boot and the military uniform supply OCP tactical combat boots. The hypothesis of this study is that the personal sneakers will provide the maximum shock absorbent properties over the two types of combat boots.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary study endpoint is to assess impact loading in three types of footwear to determine which has the greatest shock absorption properties.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

NA
2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

Currently, injury risk factors include, recruits’ fitness level before boot camp, gender, age, anatomical factor. The anatomical factors and gender are the primary focus on injury risk because of the different anatomical structures lead to overuse injuries in females.

2.2 Previous Data

Describe any relevant preliminary data.

Preliminary data indicates that females have a higher injury rate because of wider hips leading to a greater valgus angle. Impact loading is a big contributor to injury.

2.3 Study Rationale

Provide the scientific rationale for the research.

The rationale for this study was to assess impact loading and injury risk in three types of footwear, this information may be used to design training interventions to reduce injury occurrence in military trainees.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in
your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children** – Review “HRP-416- Checklist - Children”
- **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
- **Cognitively Impaired Adults** – Review “HRP-417- Checklist - Cognitively Impaired Adults”
- **Prisoners** – Review “HRP-415- Checklist - Prisoners”
- **Neonates of uncertain viability or non-viable neonates** – Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

### 3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.).

Females between the ages of 18 – 30 years old who are currently free of injuries to the lower musculoskeletal system. These individuals must have a running background of at least 3 miles a month. Participants should be able to fit in size 6 or 7 combat boots and be comfortable running in boots or easily adjustable.

### 3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

Individuals under the age of 18 or over the age of 30. Individuals must be in relatively good health to participate in the study. They must have adequate physical fitness to complete the brief bouts of running, some history of running, no injuries to the lower extremities, and no cardiovascular limitations. BMI and blood pressure will not be used to exclude participants. If the participants can’t fit into size 6 or 7 combat boots nor adjust to running in combat boots, they will be excluded from this study. Men are excluded from this study as the injury mechanisms in military recruits differ dramatically by gender, and this study is only looking at impact loading, which specifically affects females. Pregnant women will be excluded.

### 3.3 Early Withdrawal of Subjects

#### 3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Individuals will be removed from this study if they withdraw their consent to participate. If the participants can’t fit into the combat boots nor adjust to running in combat boots, they will be excluded from this study.
3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

No follow-up will be conducted from withdrawn subjects.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

Potential subjects will be recruited from Penn State Berks campus along with the locals in Berks County.

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (http://irb.psu.edu). See “HRP-103-Investigator Manual, What is appropriate for study recruitment?” for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Participants will be orally recruited as well as flyers at local facilities in Berks County. After they are recruited, the participants will have time to review the criteria of this study before consenting to participate. If they are interested in participating, the participants can contact the research team to notify their interest in the study.
4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participate in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

4.2.1 How potential subjects will be recruited.

Potential subjects will be recruited by a recruitment script, letter and by flyers. The local community will be utilized to recruit participants by physical visiting the local areas such as gyms and recreational facilities to hand out flyers and request contact information to send out recruitment letters by email.

4.2.2 Where potential subjects will be recruited.

Potential subjects will be recruited from Penn State Berks campus from kinesiology classes and the campus gym with a recruitment speech as well as the local Berks communities such as gyms and recreational facilities with flyers and recruitment letters emailed to gyms and fitness groups.

4.2.3 When potential subjects will be recruited.

Subjects will start being recruited after IRB approval

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]

An eligibility screening questionnaire will be used to determine eligibility prior to consent.

5.0 Consent Process and Documentation

Refer to the following materials:

- The “HRP-091– SOP - Written Documentation of Consent” describes how the consent process will be documented.
- The “HRP-314- Worksheet - Criteria for Approval” section 7 lists the required elements of consent.
• The “HRP-312- Worksheet - Exemption Determination” includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.

• The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.

• Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State’s consent templates are available in the same location where they are uploaded. DO NOT include the actual consent wording in this protocol.

5.1 Consent Process:

Check all applicable boxes below:

☑ Informed consent will be sought and documented with a written consent form [Complete Sections 5.2 and 5.6]

☐ Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) [Complete Sections 5.2, 5.3 and 5.6]

☐ Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). [Complete section 5.2, 5.4 and 5.6]

☐ Informed consent will not be obtained – request to completely waive the informed consent requirement. [Complete Section 5.5]

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in “HRP-312- Worksheet- Exemption Determination.” Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in “HRP-590- Consent Guidance for Exempt Research”):

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete): The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator’s assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB
Review (see “HRP-312- Worksheet- Exemption Determination”) is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Describe where and when the consent process will take place.

The subject will be consented when they first arrive at the laboratory.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

There will be no judgement on their decision to participate or not. Participation in this study is voluntary and participants can withdraw at any time.

5.3 Waiver of Written Documentation of Consent

Review “HRP – 411 – Checklist – Waiver of Written Documentation of Consent.”

NA

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered

NA

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

NA

5.4.3 Describe why the research involves no more than minimal risk to subjects.

NA
5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

NA

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

NA

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

NA

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

NA

5.5.2 Describe why the research involves no more than minimal risk to subjects.

NA

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

NA

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

NA
5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate “not applicable.”

NA

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review “HRP-091 –SOP- Written Documentation of Consent” and “HRP-103 -Investigator Manual” to ensure that you have provided sufficient information.

Individuals who do not have verbal command of the English language will not be recruited for this study.

5.6.2 Cognitively Impaired Adults

Refer “HRP-417 -CHECKLIST- Cognitively Impaired Adults” for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

NA

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state of Pennsylvania, review “HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of...
Pennsylvania meet the definition of “legally authorized representative.”

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013 -SOP- Legally Authorized Representatives, Children, and Guardians.”

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission.

Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state of Pennsylvania, review “HRP-013-SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “children.”
For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians.”

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

NA

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See “HRP-103 - Investigator Manual” for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study. [Mark all parts of sections 6.2 and 6.3 as not applicable]
Authorization will be obtained and documented as part of the consent process. [If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]

Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained). [Complete all parts of sections 6.2 and 6.3]

Full waiver is requested for entire research study (e.g., medical record review studies). [Complete all parts of sections 6.2 and 6.3]

Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained). [Complete all parts of sections 6.2 and 6.3]

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Information is included in the “Confidentiality, Privacy and Data Management” section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.
6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

NA

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alteration of authorization.

NA

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the ‘Minimum Necessary’ standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). DO NOT include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

[Do not type here]

7.1 Study Design

Describe and explain the study design.
This study will analyze the vertical ground reaction force components while female test subjects where three types of footwear.

7.2 **Study Procedures**

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- **HOW:** (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
- **WHERE:** (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

The first thing the participants do when they enter the testing facility is give formal consent by signing the consent form. Next the participants will be fitted to the two types of combat boots being testing. One boot being tested is the Belleville 390DES hot weather combat boot, and the other boot tested was the military uniform supply OCP tactical boot. The combat boots will be rated on a comfort scale 1-5 (1 being uncomfortable and 5 being comfortable) using a paper survey.

During data collection, the participant will first wear their personal running shoes and stand on the force plate to achieve their individual gravitational force. Then the subject will warm up by running down the 7 meter long runway at their jogging pace. After the test subject is warmed up, 5 successful trials will be recorded. Next the combat boots will be selected at random to start collecting data. For each combat boot, the participant will get a chance to warm up and adjust to the weight difference of the boots, and repeat the 5 jogging trials across the runway.

7.2.1 **Visit 1 or Day 1 or Pre-test, etc.**

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

Participants will come to the kinesiology laboratory in the Beaver Community Center. Once participants have signed the proper paperwork consenting to participate in the study, they will try on different brands of combat boot to find the appropriate size. They will begin by running down the 7-meter runway, across the force plate in their sneakers to warm up and adjust to the running environment. Then data will be collected as they run across the force plate 10-15 times in their running sneakers. Next, they will put on one of one pair combat boots and practice a couple of times running down the 7-meter path across the force plate. Once they are comfortable running in the combat boots, more data will be collected as they run across the force plate 10-15 times. The test subjects will do a practice one more time in the second pair of
combat boot, then data will be collected again as they run across the force plate 10-15 times. There will be 1-2 minutes of rest between each footwear condition to prevent fatigue.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)
Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).
NA

7.3 Duration of Participation
Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Participation will be approximately 1 hour for each individual. After they participate, the individuals do not have to return and perform the study again.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects
Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

One hundred subjects will be enrolled in this study.

8.2 Sample size determination
If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Previously published studies indicate this is an appropriate number of subjects

8.3 Statistical methods
Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

One way repeated measures ANOVA will be employed since we are comparing three types of footwear

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in “HRP-001 SOP- Definitions.”

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily
encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.

NA

9.1 Periodic evaluation of data
Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.
NA

9.2 Data that are reviewed
Describe the data that are reviewed, including safety data, untoward events, and efficacy data.
NA

9.3 Method of collection of safety information
Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).
NA

9.4 Frequency of data collection
Describe the frequency of data collection, including when safety data collection starts.
NA

9.5 Individuals reviewing the data
Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
NA

9.6 Frequency of review of cumulative data
Describe the frequency or periodicity of review of cumulative data.
NA
9.7 **Statistical tests**

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

NA

9.8 **Suspension of research**

Describe any conditions that trigger an immediate suspension of research.

NA

10.0 **Risks**

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks.

Note: Loss of confidentiality is a potential risk when conducting human subject research.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

During the data collection process, the participant may experience local fatigue due to the nature of the testing. The fatigue would be physical in nature. Running in the laboratory can present some risk of injury such as falling, hitting objects, and tripping. However, participants will be able to familiarize themselves with the locations and running across the force plates, thus participation in research will not be present additional risk. The study team will be asking if the participant is comfortable throughout the duration of the data collection as well as making sure that before the assessment occurs, they understand what they will be expected to do for the data collection. If the subject begins to feel uncomfortable, we will stop the protocol immediately and discuss whether further data collection should occur. There may be a risk of loss of confidentiality but to ensure this doesn’t happen the subjects data will be randomly assigned a subject ID that will have no connection to the subjects identity, and no images of the subject will be collected.

11.0 **Potential Benefits to Subjects and Others**

11.1 **Potential Benefits to Subjects**

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.
11.2 Potential Benefits to Others

Include benefits to society or others.

Potential benefits of this study include a way to help military members in adjusting their footwear to prevent injuries.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how information will be shared.

If asked, the PI will explain the data to the subject. If the PI discovers something potentially harmful to the subject with the data the subject will immediately be notified and urged to seek professional medical attention. If the subject wants, they may leave their contact information with the PI so that a copy of the published study can be furnished with and if it is published.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is no subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

No subject stipend or travel reimbursement will be offered

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

NA
14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

It is the policy of the institution to provide neither financial compensation for free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Cost for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator’s experience conducting research at these locations and familiarity with local culture.

The research will be conducted in the Kinesiology Laboratory at Penn State Berks. This location allows the PI to provide privacy to the subjects in the form of closing doors between the lab and public space. The space has a force plate which will be uses to measure the variables needed for this study.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.
The research team has access to the women student body at Penn State Berks as well as the local community. Therefore, it is feasible that the research team will be able to recruit the number of subjects needed for this research.

**15.3 PI Time devoted to conducting the research**

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI is an Assistant Profession with 45% of her time dedicated to research and will, therefore, have time to devoted to this research. The research coordinator is an undergraduate student working on this research for her senior thesis and will have time to devote to this research.

**15.4 Availability of medical or psychological resources**

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

There is a nurse practitioner, athletic trainer, and psychological counseling services on the Berks campus as well as the PI who is also first aid and CPR certified, in the unlikely event that a subject needs these resources. If a participant should fall during the research trials, the nurse or the athletic trainer will be called and asked to come make sure the participant is okay.

**15.5 Process for informing Study Team**

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

If a new research team member is added to this study, after finishing their IRB training the PI will train them and inform them of their duties. The new team members will be informed about the consent forms, questionnaires, and screening questions that all the participants fill out, along with being walked through the procedure for testing participants. New team members will also be familiarized with keeping the participants information private and keeping a professional environment.

**16.0 Other Approvals**

**16.1 Other Approvals from External Entities**

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

na
16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – Penn State Health only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of “HRP-902 - Human Tissue For Research Form” in CATS IRB.

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – Penn State Health only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of “HRP-901 - Human Body Fluids for Research Form” in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Penn State Health only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of “HRP-903 - Radiation Review Form” in CATS IRB.

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Penn State Health only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.
17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

NA

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site’s IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

This is not a multi-site study

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

NA

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

NA

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

NA
17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

NA

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If NOT applicable, indicate as such below in all sections.

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

NA
20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

NA

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

NA

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

NA

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

NA

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

NA

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete “HRP-598 Research Data Plan Review Form.” In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using “HRP-598 – Research Data Plan Review Form.”
Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data,” which is available on the IRB’s website. In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: complete the following section. Please refer to [PSU Policy AD95](mailto:PSU Policy AD95) for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State’s Policy AD95 or standards or need a consultation regarding data security, please contact [security@psu.edu](mailto:security@psu.edu).

### 22.1 Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

<table>
<thead>
<tr>
<th>Hard Copy Data</th>
<th>Electronic Stored Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names and/or initials (including on signed consent documents)</td>
<td>☒</td>
</tr>
<tr>
<td>All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,</td>
<td>☐</td>
</tr>
<tr>
<td>All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older</td>
<td>☐</td>
</tr>
<tr>
<td>Telephone numbers</td>
<td>☐</td>
</tr>
<tr>
<td>Fax numbers</td>
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<tr>
<td>Electronic mail addresses</td>
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<tr>
<td>Social security numbers</td>
<td>☐</td>
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<tr>
<td>Medical record numbers</td>
<td>☐</td>
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<tr>
<td>Health plan beneficiary numbers</td>
<td>☐</td>
</tr>
<tr>
<td>Account numbers</td>
<td>☐</td>
</tr>
</tbody>
</table>
22.2 If storing paper records of research data, answer the following questions:

22.2.1 Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

Signed consent forms and boot comfort surveys will be stored in a locked filing cabinet in the PI’s office.

22.2.2 How will the paper records be secured?

Filing cabinet is inside of a locked office and to cabinet will be locked with access only to the PI.

22.2.3 How will access to the paper records be restricted to authorized project personnel?

Only the PI will have access.
22.3 If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

- Penn State-provided database application. Check which of the following database applications are being used (check all that apply):
  - [ ] Penn State REDCap
  - [ ] Other – Specify - provided and approved database application:

- [ ] Penn State, College, or Department IT file server
- [ ] Box.psu.edu (Apply for a Box NPA here: https://box.psu.edu/non-person-account/)

- [ ] Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:

- [ ] Other – Specify the database application or server:

  Provide details about the data security features or attach security documentation provided by sponsor or group:

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

22.4 Is there a list/key that links code numbers to identifiers?

- [ ] Yes - explain how the list that links the code to identifiers is stored separately from coded data:

- [ ] Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.
  no identifiers will link to the data in any way

22.5 Is there a list of people who have access to the list/key?

- [ ] Yes – explain how access to that list is restricted and why certain persons require access.

- [ ] No – explain why not:
22.6 Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

- Password-protected files
- Role-based security
- Specify all other mechanisms used to ensure only permitted users have access to the stored research data.
  - Traditional lock and key

The use of mobile devices or wireless activity trackers to collect identifiable research data must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu to confirm approval.

22.7 Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

- No
- Yes - answer the following questions:

22.7.1 Specify the provider of the mobile devices(s)

- Supplied by the sponsor
- Penn State owned device
- A personal device
- Other – Please specify source:

22.7.2 Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

22.7.3 Specify the type of data collected on the mobile devices(s).

22.7.4 Specify the application or website used to collect the data from the mobile device, if applicable.

22.7.5 Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu.
22.8 Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

☐ No
☐ Yes - answer the following questions:

22.8.1 Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

22.8.2 Specify the type of data collected over the internet or via email.

22.8.3 Describe the measures taken to protect the confidentiality of the data collected?

22.8.4 Describe how the research team will access the data once data collection is complete.

22.8.5 If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

☐ Penn State REDCap
☐ Penn State Qualtrics (de-identified data only)
☐ Other - Please specify:
  Application:
  URL (If applicable):

22.8.6 If the answer above is “Other” contact security@psu.edu for approval of an alternative data capture method

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact the Office of Information Security at security@psu.edu to confirm whether these requirements are required.

22.9 Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

☐ No - skip to section 22.10
Yes - answer the following questions:

22.9.1 What will be used to capture the audio/video/images? Give a brief description of content.
- Audio – Describe the intended content of the audio recording:
- Video – Describe the intended content of the video recording:
- Photographs of the subjects – Describe the intended content of the photographs:
- 3-D Images – Describe the intended content of the 3-D images:
- Other - Specify:

22.9.2 How will the recordings/photographs/images be stored (electronically or physically)?

22.9.3 Where will the recordings/photographs/images be stored?

22.9.4 Who will have access to the recordings/photographs/images?

22.9.5 Will any of the recordings be transcribed?
- Not applicable
- No
- Yes – indicate who will be doing the transcribing?

22.9.6 Will the recordings/photographs be used for purposes other than this research study?
- No
- Yes - specify purpose(s) (e.g., publication, presentations, educational training, future undetermined research):

22.10 Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?
- Yes - check one of the following:
  - The research involves human subjects as defined by the DHHS regulations (See Worksheet
The research involves collecting or using biospecimens that are identifiable to an individual. If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual. The research involves the generation of individual level, human genomic data.

Note: If any of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.

No - answer the following question.
If the research is not funded by NIH, will the investigator apply for a COC for this research study?
☒ No
☐ Yes

Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.

22.11 What steps will be taken to protect subjects’ privacy interests? (Check all that apply.)
☒ Identification and recruitment of potential subjects follows procedures consistent with privacy standards
☒ Consent discussion and research interventions will take place in a private setting
☒ Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes
☒ Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process
☐ Other – Specify:

22.12 What is the process for ensuring correctness of data entry?
☒ Double data entry to reduce risk of errors
☒ Electronic edit checks to ensure data being entered are not obviously incorrect
☒ Random internal quality and assurance checking of research data
☒ Direct entry by subjects
☐ Other - Specify:

22.13 Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (http://gds.nih.gov)?
☒ No
Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

22.14 The European Union (EU) General Data Protection Regulation (GDPR)

22.14.1 To determine if the research is subject to the GDPR answer the following questions:

22.14.1.1 Will the Penn State principal investigator, or another entity under the Penn State principal investigator’s direction, be collecting, recording, storing, using, any personal data* of any subjects physically located in the European Economic Area (EEA)** at the time of data collection (even if the subject is NOT an EEA resident) or any EEA citizens? (This includes recruitment through social media sites, use of third party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)

☐ No
☐ Yes (This research may be subject to the GDPR)

22.14.1.2 Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

☐ No
☐ Yes (This research may be subject to the GDPR)

22.14.2 If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

22.14.2.1 Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

☐ No
☐ Yes

22.14.2.2 Will any of the data be related to criminal convictions or offenses?

☐ No
Comments on any of the above responses:

* “Personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

** European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

22.15 Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

☐ No - skip the remainder of section 22.15.

☐ Yes - answer the following questions.

Check all that apply:

☐ **Data** are being transferred or disclosed to Penn State
   What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

   Is the third party requiring us to sign a contract regarding the data?
   ☐ Yes - If Yes, this contract must go through the Office of Sponsored Programs
       https://www.research.psu.edu/osp/overview-pages/data-use-agreements
   ☐ No

☐ **Data** are being transferred or disclosed from Penn State
   What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

   Note: Data transfers or disclosures may require a Data Use Agreement (DUA).

☐ **Specimens** are being transferred to Penn State
   What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

☐ **Specimens** are being transferred from Penn State
What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA). Please contact the Office of Technology Management for more information.

22.15.1 Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

22.15.2 How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

22.15.2.1 Data being transferred or disclosed to Penn State:

- [ ] Data are being received in aggregate/metrics (just counts, no individual data)
- [ ] De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- [ ] Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- [ ] Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list
- [ ] Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list
- [ ] Data with identifiers along with the linking list are being received
- [ ] Other – Specify:

22.15.2.2 Data being transferred or disclosed from Penn State:

- [ ] Data are being sent in aggregate/metrics (just counts, no individual data)
De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list

Data with identifiers along with the linking list are being sent

Other – Specify:

22.15.2.3 Specimens being transferred or disclosed to Penn State:

De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

Coded specimens with identifiers along with the linking list are being received

Other – Specify:
22.15.2.4 Specimens being transferred or disclosed from Penn State:

- De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)
- Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list
- Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list
- Coded specimens with identifiers along with the linking list are being sent
- Other – Specify:

22.15.3 If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

<table>
<thead>
<tr>
<th>Identifiers</th>
<th>Medical record numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names</td>
<td>Medical record numbers</td>
</tr>
<tr>
<td>Initials</td>
<td>Health plan beneficiary numbers</td>
</tr>
<tr>
<td>Street address</td>
<td>Account numbers</td>
</tr>
<tr>
<td>City</td>
<td>Certificate/license numbers</td>
</tr>
<tr>
<td>Driver’s License numbers</td>
<td>Passport numbers</td>
</tr>
<tr>
<td>State</td>
<td>State ID numbers</td>
</tr>
<tr>
<td>Zip Codes</td>
<td>Vehicle identifiers and serial numbers, including license plate numbers</td>
</tr>
<tr>
<td>County</td>
<td>Device identifiers and serial numbers</td>
</tr>
<tr>
<td>Geocodes</td>
<td>Web Universal Resource Locators (URLs)</td>
</tr>
<tr>
<td>Precincts</td>
<td>Internet Protocol (IP) address numbers</td>
</tr>
<tr>
<td>All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death</td>
<td>Biometric identifiers, including finger and voice prints</td>
</tr>
<tr>
<td>Ages &gt; 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older</td>
<td>Full face photographic images and any comparable images</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th><strong>Telephone numbers</strong></th>
<th><strong>Any other unique identifying number, characteristic, or code (such as the pathology number)</strong> Specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fax numbers</strong></td>
<td><strong>Study code numbers</strong></td>
</tr>
<tr>
<td><strong>Electronic mail addresses</strong></td>
<td><strong>Master list linking study code numbers to subject(s)</strong></td>
</tr>
<tr>
<td><strong>Social security numbers</strong></td>
<td><strong>Genomic sequence data</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Other – specify:</strong></td>
</tr>
</tbody>
</table>
Appendix B

Recruitment Speech

Script for recruitment:

Hello, my name is Courtney. I am a student in the Kinesiology Program at Penn State Berks. I am doing a study to assess the impact loading rate of two types of combat boots in female between the ages of 18 and 30. The purpose of this study is to assess injury risk through impact loading with two types of military issued footwear during running. The results of this study can be used to mitigate injuries by changing the footwear used by the military or increasing the time recruits spend in sneakers. Participation in this study is strictly voluntary, but we do hope to gather at least 20 test subjects. The study will take less than an hour. Your participation in this study will help to examine the impact loading on the lower extremities while wearing three types of footwear and may help to design interventions for military personnel in the future. Do you have any questions? If you have any additional questions, you can contact me at cmh6314@psu.edu or my thesis advisor, Dr. Singles at ara5093@psu.edu.
Appendix C

Recruitment Flyer

The Effect of Various Military Issued Footwear on Impact Loading During Running

● Participants wanted (need to meet the following requirements)
  ✓ Females
  ✓ Between the ages of 18 and 30
  ✓ No major injuries or surgeries

● Participation will require 1 hour with an undergraduate researcher

● Running will be measured using a force plate

● Information can be used to minimize injury risk for military personnel

Please contact Courtney Hoopert at cmh6314@psu.edu with any questions, comments, or concerns.
Appendix D

Screening Questions

Screening questions: Can you answer no to the following?

1. Are you younger than 18 or older than 30?

2. Do you have any musculoskeletal injuries to your lower extremities that would impact your ability to run?

3. Would you be uncomfortable running in boots?

4. Do you run less than 3 miles per month?

5. Are you uncomfortable jogging across a 7m runway several times in the span of one hour? (Rest will be provided between trials.)

6. Do you have any cardiovascular limitations or limitations to your physical fitness that would influence your ability to run as stated previously?

7. Would you be uncomfortable running in size 6 or 7 combat boots? (Boot sizing is similar to men’s shoe sizes)

8. Are you pregnant?

The PI or a co PI will ask the screening questions. All are qualified to determine if a condition would constitute an impairment that would disqualify a potential participant.
Title of Project: The effect of Various Military Issued Footwear on Impact Loading During Running  
Principal Investigator: Allison Singles  
Address: Penn State Berks, Thun Library, P.O. Box 7009, Tulpehocken Road, Reading, PA 19610  
Telephone Number: 610-396-6152  
Advisor: Allison Singles  
Advisor Telephone Number: 610-396-6152  
Subject’s Printed Name: ____________________________

We are asking you to be in a research study. This form gives you information about the research.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

   The purpose of this study is to assess injury risk through impact loading with three types of military issued footwear during running. The objective is to analyze female test subjects ground reaction force as they run across force plates. These test subjects will be wearing their personal running sneakers to achieve a base line ground reaction force, then run across the force plate with Belleville 390DES hot weather combat boot desert tan, and the military uniform supply OCP tactical boot-coyote combat boots. The hypothesis of this study is that the personal sneakers will provide the maximum shock absorbent properties over the two types of combat boots.

2. What will happen in this research study?

   After you sign this consent form the following will take place:

   ● Two types of combat boots will be tried on to find your appropriate size.
- You will perform a warmup in your sneakers by practice running down the 7-meter runway across the force plates.
- Once you are comfortable with the running environment, data will be collected as you run across the force plate in your sneakers.
- You will run across the force plate in sneakers for 10-15 trials.
- Then one combat boot at a time, you will put them on and adjust to running in them down the 7-meter runway across the force plates.
- Data will be collected from each combat boot as you run across the force plate.
- You will run across the force plate in one combat boot for 10-15 trials.
- The trials will be repeated one more time by running across the force plate in the second combat boot for 10-15 trials.
- You will be able to rest 1-2 minutes in between each footwear condition.
- Once you have completed all the footwear conditions you will be asked to rate the comfort of the boots.

3. **What are the risks and possible discomforts from being in this research study?**

   During the data collection process, you may experience local fatigue due to the nature of the testing. The fatigue would be physical in nature. Running in the laboratory can present some risk of injury such as falling, hitting objects, and tripping. However, you will be able to familiarize yourselves with the locations and running across the force plates, thus participation in research will not be present additional risk. I will be asking if you are comfortable throughout the duration of the data collection as well as making sure that before the assessment occurs you understand what you’re expected to do for the data collection. If you begin to feel uncomfortable, I will stop the testing immediately and discuss whether further data collection should occur.

   There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. **What are the possible benefits from being in this research study?**

   4a. **What are the possible benefits to you?**

      The potential benefits of this study include a sense you are helping further research. Also, a deeper understanding of human biomechanics.

   4b. **What are the possible benefits to others?**

      This study may lead to improvement in the combat boots used by our military members.

5. **What other options are available instead of being in this research study?**

   You may decide not to participate in this research at any time.
6. How long will you take part in this research study?

Being in this research study may take up to sixty minutes to complete and it is one study visit.

7. How will your privacy and confidentiality be protected if you decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information.

- Your research records will be labeled with a random subject ID number that will have no connection to the participants identity and will be kept in a locked file cabinet in the private investigators office or on a password protected network server.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about your participation in this research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The Institutional Review Board (a committee that reviews and approves research studies) and
- The Office for Research Protections.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed.

7b. What will happen to my research information and/or samples after the study is completed?

We may use your research information force plate data for future research studies or may share your data with other investigators here or at other institutions for future research without
your additional informed consent. Future research may be similar to this study or completely different. Before we use or share your information or samples we will remove any information that shows your identity.

8. **What are the costs of taking part in this research study?**

8b. **What happens if you are injured as a result of taking part in this research study?**

In the unlikely event you become injured as a result of your participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By signing this document, you are not waiving any rights that you have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators.

9. **Will you be paid or receive credit to take part in this research study?**

There will be no financial compensation to take part in this research study.

10. **Who is paying for this research study?**

Pennsylvania State University Berks campus will be funding this research.

11. **What are your rights if you take part in this research study?**

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- Not able to fit in the combat boots or being able to adjust to the combat boots

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. **If you have questions or concerns about this research study, whom should you call?**

Please call the head of the research study Allison Singles at 610-396-6152 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, ORProtections@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

**INFORMED CONSENT TO TAKE PART IN RESEARCH**

**Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

______________________________  _________  ________________
Signature of person who explained this research  Date   Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

**Signature of Person Giving Informed Consent**

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

**Signature of Subject**

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

______________________________  _________  ________________
Signature of Subject     Date   Printed Name
Appendix F

Comfort level

**Boot Comfort Survey**

Please rate your comfort in the footwear used during this study

<table>
<thead>
<tr>
<th></th>
<th>totally uncomfortable</th>
<th>totally comfortable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sneakers</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>Belleville Boots</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
<tr>
<td>OCP Boots</td>
<td>1 2 3 4 5</td>
<td></td>
</tr>
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</table>
BIBLIOGRAPHY


doi:10.7205/milmed-d-12-00432

doi:10.1097/jsm.0b013e3181b8c270

doi:10.1097/jsm.0b013e3181b8c270

ACADEMIC VITA

Courtney Hoopert
Cmh6314@psu.edu

Education

The Pennsylvania State University
B.S. in Kinesiology – Exercise Science

With honors in Kinesiology

Fall 2016 – Spring 2020

Thesis Title: The effect of various military issued footwear on impact loading

Thesis Supervisor: Dr. Allison Altman-Singles

Awards and Honors

Dean’s List

Fall 2016 - Spring 2020

Boscov Scholarship

Fall 2018 - Spring 2020

Penn State Academic Grant

Fall 2018 - Spring 2019

Publications

Hoopert, C. M., Mercer, J. D., Chang, B. P., Filby, S. W., Ragland, J. M., Altman-Single, A. R.
Impact loading in youth athletes is similar in males and females. Abstract submitted to the 2019 Annual Meeting of the American Society of Biomechanics East Coast conference, Penn State Berks, PA, 2019.

Mercer, J. D., Hoopert, C. M., Chang, B. P., Filby, S. W., Ragland, J. M., Altman-Single, A. R.


Presentations

Hoopert, C. M., Mercer, J. D., Chang, B. P., Filby, S. W., Ragland, J. M., Altman-Single, A. R.
Impact loading in youth athletes is similar in males and females. Poster presentation at the 2019 Annual Meeting of the American Society of Biomechanics East Coast conference, Penn State Berks, PA, 2019.

Mercer, J. D., Hoopert, C. M., Change, B. P., Filby, S. W., Ragland, J. M., Altman-Single, A. R.
Do more active youth have lower impact loading during running? Poster presentation at the 2019 Annual Meeting of the American Society of Biomechanics East Coast conference, Penn State Berks, PA, 2019.

Work Experience

United States Navy – worked as an aviation electronics technician on jets

Active duty

Feb 2011- May 2016

Reserves

Jun 2016 –Present

Volunteer Experience

IM Able Foundation- provides equipment for adaptive athletes

Spring 2018 – Present

Triathlon – fundraising event

May

Duathlon – fundraising event

October

Bash – fundraising event

March - 2019

Blue Marsh Trails

Spring - 2018
Performed trail maintenance which included rerouting a stream and building a bridge