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Brendan J. Rickert Sacred Heart University, rickertb@sacredheart.edu

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## SACRED HEART UNIVERSITY

## COLLEGE OF HEALTH PROFESSIONS

# TIBIAL ACCELERATION IN MALE AND FEMALE DISTANCE RUNNERS IN REDUCED BODY WEIGHT CONDITIONS

By

Brendan J. Rickert, B.S., H.F.S.

A Thesis submitted to the

Department of Physical Therapy and Human Movement Sciences

in partial fulfillment of the requirements for the degree of

Master of Science in Exercise Science and Nutrition

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# TIBIAL SHOCK IN MALE AND FEMALE DISTANCE RUNNERS IN REDUCED BODY WEIGHT CONDITIONS

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## ABSTRACT

Seventy-two percent of all stress fractures in athletes come from running, which can cause an immediate cessation of training. Additionally, fifty

percent of all stress fractures occur in the distal end of the tibia. One way to keep the athlete moving without slowing down the healing process is using an unloader treadmill (TM) in a rehabilitation setting. The purpose of this study was to investigate relationship between the level of body weight (BW) unloading in an Anti-Gravity Treadmill and tibial acceleration. Fifteen collegiate cross-country team runners (Gender: 9 males, 6 females; Age:  $20.4 \pm 2.4$  years; Weight  $60.1 \pm 12.6$  kg) were recruited for this study. Tibial acceleration was assessed through a skin-mounted accelerometer which was attached to the lower third of the tibialis. Results show no significant difference between mean peak tibial acceleration from a 100% BW to 60% BW conditions. There was a significant ( $p \le 0.05$ ) difference from 100% BW to 60% BW in mean peak to peak accelerations, which is indicative of tibial stress. Additionally, significant differences were observed among stride rate and heart rate which decreased throughout all BW conditions which shows changes kinetic and metabolic demands. In order to effectively reduce tibial stress in runners, a runner would have to start at or below 60% of their BW. Tibial acceleration was not reduced due to the kinetic changes which occurred from a reduction in BW.

## **INTRODUCTION**

Long distance running has become a popular form of exercise for all levels of participants. Over 25 million Americans run 50 days or more yearly and of those, almost 16.5 million participate at least 100 days a year.<sup>47</sup> Twenty-four to 65% of all runners report a running-related injury (RRI) every year that results in a minimum of five consecutive days off.<sup>23</sup> A RRI has previously been defined as the following: "if they had pain or symptoms during or immediately after a run, onset of symptoms at the beginning of a new training program, if injury was felt to be related to running and/or, injury was significant enough to force them to stop running or significantly reduce their running frequency and duration and seek medical assistance."(Pg. 96)<sup>50</sup>

Runners experience 2-2.5 times their body weight (BW) upon impact during the stance phase of running.<sup>6</sup> Specifically, the distal tibia has 10.3-14.1 x BW of compressive forces which results in a greater risk of developing a lower leg injury.<sup>44</sup> Seventy-two percent of all stress fractures in athletes come from running, which can cause an immediate cessation of training. Additionally, fifty percent of all stress fractures occur in the distal end of the tibia.<sup>35</sup> Typically, a tibial stress fracture requires 4-6 weeks of recovery time before training can resume.<sup>27</sup>

Since 2005, Alter-G (AG) (Freemont, CA) has used NASA developed technology to create an augmented treadmill (TM) for both rehabilitative and performance purposes using differential air pressure (DAP) technology (Figure 1.1). AG TM monitors body weight with force sensors integrated with the TM base. Pressure in the air bladder can be altered to change the amount of unloading a participant experiences. Due to DAP, the participant using the TM can artificially reduce their body weight.<sup>3</sup> It is possible to alter BW from 1-80% in 1% increments. Similar models of unloader TMs have been available previously, however they are ineffective

from a performance standpoint due to their restrictive qualities.<sup>9,15,19,56,59</sup> A performance TM needs to allow for a greater range of movement as to not restrict natural running kinematics. Typical unloading TMs have devices that attach to your hips and torso to purposefully limit movement and compensate for poor posture.<sup>1</sup> The AG is designed to only support the participant's body from their hips, still allowing for the proper amount of unloading but does not modify body posture.<sup>56</sup>



Figure 1.1 : A runner using the AG TM during a training session

For rehabilitation, DAP TM have beneficial outcomes because they reduce ground reaction forces, muscular activity, and metabolic cost.<sup>1,9,19</sup> This allows a wide range of

populations to use this tool in order to improve everyday function and performance.<sup>9,19</sup> Unloading TM's are often used with people with neurological problems, orthopedic injuries, obesity, low exercise tolerance, disease states, and to enhance performance. Because of the AG's unique design that allows it to be used for performance training, and with its rehabilitative benefits, this TM could potentially be used to maximize recovery time for competitive athletes and still provide a training stimulus. With the exception of case-studies, there has been limited investigation of AG TM rehabilitation protocol standards.<sup>22</sup> Dr. Saxena, a podiatrist, reported the frequent uses of AG TM for various orthopedic and musculoskeletal injuries in hopes to reduce recovery time. His research comes from reported rehabilitation protocol which was developed through trial & error.<sup>45</sup> Similar case-studies have been published that have shown treatment progression for various injuries but these studies have been limited.<sup>3,36,58</sup>

Due to the frequency of stress fractures occurring at the distal end of the tibia, it is important to understand the physical stress placed on the tibia during running and how to protect it during a rehabilitation program. While running, even though the 2-2.5 times BW force are partially dissipated by the shoe's midsole, the distal end of the tibia undergoes 10.3-14.1 BW of compressive force.<sup>44</sup> This high compressive force was due to the musculature around the tibia and how it pulls and moves around the bone in order to keep the running cycle moving. The tibia has the highest force value compared to other lower extremity bones due to its proximity to the impact and loading.<sup>26</sup> Typical rehabilitation programs for tibial stress fractures start with a short-term use of a walking boot or air cast for daily activities.<sup>57</sup> The boot and cast allow for the redistribution of forces.<sup>14</sup> After a period of approximately three weeks of using a boot or cast, an additional 1-5 weeks of non-impact physical activity is required.<sup>57</sup> Once bony tenderness

subsides, the patient may begin a gradual return to normal activity. The time from injury to full release to normal activity takes 8-12 weeks.<sup>57</sup>

Tibial stress is related to many factors such as fatigue, foot strike, terrain, and footwear.<sup>7,13,21,29,32-35,43,46</sup> Tibial stress is indirectly assessed by measuring tibial acceleration, which can be measured through the usage of a skin-mounted accelerometer. Mizrahi et al., through multiple studies, examined fatigue and terrain and how it is related to tibial stress, which is also known as tibial shock.<sup>32,34,35</sup> The muscles and soft tissues around the bones help attenuate the impact of loading. Due to the dependence on muscular factors, fatigued running could alter muscular activity and therefore increase tibial shock.<sup>33,34,35</sup> Additionally, terrain changes, such as downhill running, can increase tibial shock due to the increase force of impact as well as fatiguing muscles due to eccentric muscle contractions.<sup>32</sup>

Foot-ground contact in running creates a rapid deceleration of the body's center of gravity. <sup>7,13,21,29,32-35,43,46</sup> This impact causes a jarring shock that travels distal (foot) 9g's to proximal (head) 1g's of acceleration. Attenuation is the absorption of the shock throughout the body from the foot to head. A deficient shock attenuation ability of the soft tissues has been related to an increased incidence of femoral and tibial stress fractures in elite infantry recruits.<sup>32</sup> Tibial shock occurs, and must be attenuated, at every ground contact during the loading phase of running.<sup>32,40</sup>

Although several studies have measured tibial shock in full BW conditions, no studies to date have examined tibial shock in reduced BW conditions. It is assumed that if there were a reduced ground reaction force during running, then there would be a direct decrease in tibial shock. This result would be useful for prescribing AG TM rehabilitation protocols for tibial stress fractured individuals.

The purpose of this study was to investigate relationship between the level of BW unloading in the AG TM and mean peak tibial acceleration (PTA). As a result of the present study, it may be possible to prescribe more appropriate rehabilitation programs that could potentially reduce rehabilitation time and better maintain cardiovascular fitness. It is hypothesized that there was a direct relationship between reduced BW in an AG TM and tibial shock, in other words, as BW levels decreased, tibial shock would decrease.

## **REVIEW OF LITERATURE**

The review of literature begins with a brief overview of running biomechanics and possible relationships to RRI. An examination of tibial shock and its relation to the many factors of running will be explored. Additionally, DAP technology and application will also be examined. The review is concluded with comparisons of investigations previously examining similar concepts and their impacts on the current study.

### **RUNNING BIOMECHANICS**

Running gait is highly individualized based on various muscular and skeletal structures as well as landing techniques. Almost 80% of all runners are rear foot strikers (RFS), <sup>40</sup> RFS indicates that initial foot contact occurs on the outside of the heel followed by the rest of the foot landing on the ground with a rolling motion in towards the first metatarsal.<sup>6,40</sup> This type of foot strike, commonly accompanying over-striding, has an increased braking force that slows down horizontal velocity by producing a large posteriorly-directed force.<sup>6,40</sup> This braking force also results in a higher average peak vertical GRF as compared to MFS.<sup>6</sup> Initial contact with a MFS occurs approximately at 50% of the length of the foot and similar to the RFS; the foot rolls then inward towards the first metatarsal.<sup>6</sup> MFS has a reduced foot contact time compared to RFS and unlike a RFS, does not demonstrate a large braking force.<sup>6,40</sup> The third foot strike pattern, FFS, occurs when initial contact occurs on the metatarsal heads and the heel never contacts the ground. This pattern is typical within sprinting but not commonly displayed within endurance running.<sup>40</sup>

The gait cycle is split into the following two phases: swing and stance. The stance phase includes the following sub phases: initial contact (IC), loading response (LR), midstance (MS), terminal stance (TS), and preswing (PS). Similarly, the swing phase can be partitioned into the following: toe off (TO), initial swing (IS), midswing (MSW), and terminal swing (TSW).<sup>40</sup> The swing phase is about 60-70% of the gait cycle, meanwhile the stance phase is only 30-40% of the gait cycle, both of which are dependent on the speed of the runner.<sup>40</sup>

Both foot strike and running velocity influence stride rate (SR) and stride length (SL). SR and SL are inversely related from one another at the same velocity.<sup>40</sup> As previously discussed, if the SL is too long, it typically results in a RFS and a subsequent braking force.<sup>38,40</sup> As SL increases, the shock attenuation need increases requiring greater knee muscular activation to compensate for the increased load.<sup>13</sup> SR is directly related with running velocity.<sup>38</sup> Though some experts hypothesize there is an ideal step rate, around 175-185 SPM, research has not shown a set SR range that should be adhered to do the different running speed demands.<sup>10,17,18,38</sup> The greater the SL the more tibial shock that was experienced in the leg as well as throughout the body, which increases the risk for injury.<sup>21</sup> The reason for the increase in shock was due to less foot contacts and a slower leg speed.<sup>21</sup> Both height and limb length are also a factor in determining stride rate and length.<sup>38</sup>

One of the biggest running injury risks is the amount of time spent running while fatigued. Fatigued running is defined as a physiological change that results in biomechanical changes and/or as well as running above the anaerobic threshold.<sup>34,35</sup> Repeated cycles of loading during running can create overuse of both bony and soft tissues.<sup>33,34,35,43</sup> As run duration increases, especially at a speed that is faster than a typical training pace, muscles required to maintain form become fatigued and may not function as efficiently as compared to the beginning

of the run. As stated previously, the runner experiences 2-2.5 x BW when running on each step.<sup>6</sup> If the runner participates in an average training run for 40 minutes at an approximate step rate of 175 steps per minute (SPM) the runner will take approximately 7,000 steps to complete the run. The average runner runs 2-3 days/week which brings the total foot contacts for a week to 21,000 steps.<sup>47</sup> A more dedicated runner runs 6-7 days per week and typically runs for approximately 390 minutes for week and at a 180 SPM. This equates to over 70,000 steps per week.<sup>30,47</sup>

Sasimontonkul et al. examined fatigued running and its relation to tibial stress through ground reaction forces and kinematic data collection. Ten subjects ran between 3.5 and 4 m/s across a force plate both being fresh and fatigued from a self-perceived fatigued running bout. Compressive and tensile forces increased with fatigued running which increased the risk of failure on the posterior tibia from 15.48±2.56 BW to 16.07±2.44 BW and the anterior tibia from 27.00±4.95 BW to 27.94±4.01 BW. This information is especially important for competitive distance runners who are trying to increase their training volume or trying new running distances.

#### **TIBIAL SHOCK**

During the foot contact phase of running, the body absorbs the force of impact. The majority of impact is absorbed in the lower and upper leg.<sup>35</sup> Due to the increase of shock loading in the long bones of the lower limbs (tibia, fibula, femur), there is an enhanced risk of stress fractures.<sup>32</sup> The lower leg has 10.3-14.1 BW of compressive forces which results in a greater risk of developing a lower leg injury.<sup>44</sup> Seventy-two percent of all stress fractures in athletes

come from running, which can cause an immediate stoppage of training, and 50% of those occurring in the distal end of the tibia.<sup>35</sup>

Tibial shock measures the amount of acceleration experienced during foot contact. Though this does not directly measure the force on the tibia, it is an effective method in assessing the strain the bone is under. Tibial shock is then used to infer attenuation, which is the absorption and dissipation of the force. <sup>5,6,23-30</sup> Attenuation occurs from foot contact all the way through the body to the head. Acceleration forces at the distal end of the tibia can be as high as 9g's whereas the head only sees less than 1g's.<sup>19,36</sup> Tibial shock occurs at every ground contact during the entire loading phase of running.<sup>22,31</sup> Though tibial shock occurs throughout the entire stance phase, peak tibial shock is the most commonly assessed part due to the greatest demands on the tibia.<sup>32,34,35,40</sup>

A deficient shock attenuation ability of the muscle tissues has been related to an increased incidence of femoral and tibial stress fractures in elite infantry recruits.<sup>32</sup> Muscles surrounding the lower limbs help attenuate and dissipate the force throughout the body instead of letting bones take all the shock. Mizrahi et al hypothesized that muscular damage, through eccentric contracts and/or fatigue, causes an inability to dissipate and attenuate shock wave propagation.<sup>32</sup> Without the assistance of muscular activity, greater stress and deformation of bones can occur, which could lead to injury.<sup>32</sup>

Body positioning can also influence the attenuation of impact shock that is absorbed. Runners with low shock attenuation demonstrated greater body extension and increased shock at the head as well as lower tibial shock.<sup>7</sup> Due to a downhill grades (-3, -4, -6, -9, -12%) runners experienced an altered body positioning at impact and increased peak tibial shock.<sup>7,26,32,44</sup> Additionally, head positioning altered lower-limb movement and a more stabilized head reduced GRF and tibial shock.<sup>6,26,44</sup> In sports like running, tibial shock is not preventable, but it appears to be modifiable.

Though there are no available studies that have examined the relation of unloaded running conditions on tibial shock, there are several studies that examined running and tibial shock.<sup>6,7,13,19,26,32,34-36,43,44</sup> While running, there are many factors to consider such as SL, SF, running velocity, foot strike pattern, foot wear, run duration, and running surface; a summary of these studies is given in Table 1.

Mizrahi et al. found that tibial shock significantly increased at 15 minutes  $(10.5\pm4.7g)$  onwards when compared to first minute values  $(6.9\pm2.9g)$  as the runner became fatigued while running longer distances.<sup>34</sup> Additionally, the eccentric contractions of downhill running caused greater fatigue as compared to level running and also resulted in an increase in tibial shock.<sup>7,19,33,43</sup> Similar results were found in other studies that examined the relationship of fatigue and tibial shock and its repercussions for tibial stress fracture.<sup>35,43</sup> This is important to note for training and competition purposes as typical training terrain and race distances could result in a greater risk for injury.

Downhill running, due to the repeated eccentric contractions, also causes muscular fatigue, which in turn resulted in a higher peak tibial shock. Mizrahi et al. found that the quadriceps muscle fatigue caused alteration to running kinematics which ultimately reduced attenuation attenuation.<sup>33</sup> Due to this muscular fatigue, Chu et al., Killian, Mizrahi et al., and Davis et al. all reported increased tibial shock in downhill running as compared to flat ground running.<sup>7,11,32,35</sup>

Hamill et al. examined stride frequency and its relationship to tibial shock. Tibial shock was assessed on five different variables; preferred stride frequency (PSF), -20% of PSF, -10% of PSF, +10% of PSF, and +20% of PSF. The study reported that the PSF condition was the most efficient style of running. Interestingly, at higher stride frequencies, tibial shock was reduced as compared to PSF and lower stride frequencies.<sup>21</sup> Though not researched in the study, a higher stride frequency results in a shorter SL which may alter foot strike from a RFS to either a MFS or FFS.<sup>10,40</sup>

Foot wear can also influence tibial shock through its design features. Lafortune et al. found that when compared to barefoot or thin shoes, more compliant athletic shoes absorb more of the impact and therefore decrease tibial shock.<sup>28</sup> Additionally, Roy et al. examined shoe midsole design in regards to stiffness. The study concluded that the stiffer the shoe, the higher the forces recorded at the ankle, which resulted in more force being transferred to the tibia.<sup>41</sup> Furthermore, specific midsole materials have been known to reduce tibial shock.<sup>48</sup>

Study	<u># of Participants</u>	Peak Tibial Shock Values (g's)
Mizrahi et al 2000 <sup>35</sup>	n= 14	6.9±2.9 to 11.1± 4.2
Mizrahi et al 2000 <sup>34</sup>	n=14	6.9±2.9 to 11.1± 4.2
Hamill et al 1995 <sup>21</sup>	n=10	5.27±1.42, 5.39±1.31, 6.04±1.39,
		6.51±1.37, 6.67±1.84
Derrick et al <sup>13</sup> 1998	n=10	5.7, 5.9, 6.1, 7.9, 11.3
Chu et al <sup>7</sup> 2004	n=10	7.86±2.25, 8.46±2.84, 9.26±3.58,
		9.31±3.69, 9.64±3.40
Killian 2007 <sup>25</sup>	n=17	3.95±0.98, 4.16±1.18, 4.23±1.10,
		4.54±1.10, 4.71±1.34, 4.77±1.12,

Table 2.1: Tibial	Shock Studies
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		4.94±1.54, 4.86±1.27
Mizrahi et al 2000 <sup>32</sup>	n= 14	6.0±1.0, 6.5±1.4, 7.0±1.4, 7.3±1.4,
		9.0±0.4, 9.3±0.4
Davis et al <sup>11</sup> 2004	n= 5	4.73, 9.06
Laughton et <sup>29</sup> al 2003	n= 15	7.18±2.98, 6.78±3.14, 7.82±3.16,
		6.15±2.96,

Foot strike type, also influences tibial shock. When running in shoes, most participants have a RFS due to the cushioning properties of shoes, but due to natural shock absorption mechanisms, barefoot running typically has MFS to FFS.<sup>32,40,55</sup> As shown in multiple studies, RFS tends to have a higher tibial shock due to the lack of absorption which resulted in greater, direct force into the tibia, regardless of the cushioning properties of the shoes.<sup>7,19,34,35,43</sup> To help with shock attenuation, footwear has been designed with the intention of injury reduction and improved performance.<sup>49,52,54</sup> The current running trend is barefoot or minimalistic running. Barefoot has lower peak pressure under the heel due to its FFS which distributes shock more evenly throughout the foot and leg.<sup>12,49</sup> Ground contact time also affects tibial shock in a linear fashion; the more time spent on the ground, the more force the body absorbs.<sup>49</sup>

Peak to peak (PP) is an addition way of measuring tibial stress and has been reported in previous studies investigating tibial shock in running.<sup>29</sup> PP measures the total positive and negative accelerations of impact as opposed to simply tibial shock, which only measures positive accelerations. This information is useful to measure total amount of forces experienced during the stance phase.

#### **UNLOADING TREADMILLS**

Traditional unloading treadmills consist of a device that is located above the middle of the TM with ropes and a halter hanging down. The halter attaches to the participant on the upper ribs, mid-trunk, and at the waist line for the majority of support and additional straps wrap around the thigh for the unloading of the legs specifically.<sup>5</sup> Additional support may be added to the hips depending on the model and device used. A spring scale within the device measures the weight of an individual and a mechanical system adjusts through a tightening system to the desired weight loss.<sup>24</sup>

The initial design impetus for unloading condition TMs was for rehabilitative purposes.<sup>16,53</sup> This allowed the individual with a neurological or musculoskeletal disorder to relearn or improve their gait in a low fall risk and easier metabolic demanding environment.<sup>1,9,19,51,53</sup> Until the AG TM was developed, unloading TMs were generally not used for training purposes or for aggressive rehabilitation programs.<sup>15,56,59</sup>

Due to the restrictiveness of a typical unloading TM, its use in the performance setting has been minimal. The AG TM was specifically designed to allow for more natural movement. The participant is only held in place at the waist through a shorts/skirt combo that zips into the air tight bubble of the TM.<sup>56</sup> The short/skirt combo was created for the participant to move freely and still be supported by a unique, flexible, and durable material.<sup>56</sup> As compared to traditional unloading TM, AG does not restrict arm movement and does not put any pressure on the rib cage or diaphragm. Additionally, the AG does not offer support to the legs and relies solely on support at the hips, where the air is pushes against the skirt. The AG has similar

outcomes as a traditional unloading TM such as a reduced impact, decreased metabolic cost, and support.<sup>1,9,15,19,56,59</sup>

Unloading TMs were designed with Wolff's Law in mind. Wolff's Law states that bones grow and remodel in response to the forces that are placed upon it. When stress is placed on the bone, osteoblast activity increases to protect the area being stressed.<sup>60</sup> Osteoblasts help with the formation of bone. In order to get better from an injury, the injured area must become stronger which requires the use of that area. For runners with a lower leg injury, an unloading TM could potentially activate Wolff's Law and help in recovery while in a safe environment.

When the subject enters the AG and is locked into place at an appropriate height, a calibration session initially occurs. During this process, a force plate reads the subjects weight when there no DAP and at varying levels of DAP. When the pre-determined DAP asserts its force on the subjects hips, the force plate then analyzes how much less force is produced by the subject at that amount of air pressure.<sup>56</sup> Once the calibration ends, the participant can set the AG TM from 100% BW down to 20% BW at 1% intervals and depending on the model, walk or run from 0.1 MPH to 18 MPH.<sup>56</sup>

Grabowski et al. measured GRF and metabolic power at different velocities and weight support stages. Consistent with previous studies, GRF increased linearly with running velocity and metabolic costs decreased with increased unloading.<sup>20</sup> Stride frequency also decreased with decreasing weight support and foot contact time increased with decreasing rate due to the lack of metabolic demands.<sup>20</sup> Peak impact was reduced from 18-23% when level of unloading was at 50% of the subjects BW.<sup>20</sup>

Due to the decrease in BW, tibialis anterior (TA) and gastrocnemius (GA) muscle activation are also reduced in running while the AG TM.<sup>30</sup> Liebenberg et al. examined BW conditions in the AGTM and their effect on muscle activation via electromyography (EMG) sensors. Nine participants ran at a self-selected speed at 100%, 90%, 80%, 70%, and 60% of their BW. As expected the study found that reduced BW conditions yielded reduced muscle activation due to a decrease in physical demand. However, the BW percentage decrease did not lead to a linear decrease in muscle activation percentage as compared to 100%.<sup>30</sup> Additionally, when participants ran at speeds faster than their self-selected pace, muscle activity increased up to 100% BW levels of their self-selected speed regardless of the level of unloading.<sup>30</sup> The TA and GA acted in similar fashion at all levels of BW conditions with the only difference in peak average EMG readings. The TA and GA assist in shock attenuation.<sup>30</sup> These findings are similar to previous studies and further strengthen the relationship of the musculatures relationship to handle the increasing loads in order to best attenuate shock.

#### SUMMARY

High physical stresses of training runs places runners at risk for various lower-extremity RRI's, frequently to the tibia. Many factors influence the ability for the tibia to absorb the impact of running which includes SR, SL, running velocity, terrain, body positioning and muscular fatigue. Tibial shock measures the acceleration of the tibia during impact of running, which is associated with attenuation, the ability to dissipate this shock. Unloading TMs have been used for various reasons including rehabilitative purposes. Recently the AG TM has been used for both a rehabilitative and performance purposes with the potential to help athletes

decrease and maximize their rehabilitation time. There is a gap in literature in the effects of unloaded TM conditions on tibial shock.

## **METHODS**

### **Subjects**

Fifteen collegiate cross-country team runners (Gender: 9 males, 6 females; Age:  $20.4 \pm 2.4$  years; Weight 60.1 ± 12.6 kg) were recruited for this study. All participants volunteered and were members of the Sacred Heart University cross-country team. All subjects were free of lower-extremity injuries for at least six months prior to the study and had a minimum of four years of running experience. All subjects were weighed (Sunbeam Products, Boca Raton, FL) measured for height, and self-reported their leg dominance and current training history (Table 3.1). Leg dominance was determined by asking each subject their preferred kicking leg.<sup>17</sup> All experimental procedures were approved by the Sacred Heart University Institutional Review Board (Appendix B). Subjects were informed of the experimental procedures and all granted their informed consent (Appendix A). Some subjects (n= 6) had previous experience using the AG TM while the other subjects experienced the AG TM for the first time at the beginning of their data collection time.

Variable	Mean ± SD
Height (m)	$1.7 \pm 0.2$
Mass (kg)	$60.1 \pm 12.6$
Age (years)	$20.4 \pm 2.4$
Running Experience (years)	8.1 ± 3.1
Self-Reported Running Miles Per Week	$49 \pm 16$
Leg Dominance (Right Leg)	N= 14

**Table 3.1** Descriptive data for all subjects (Mean ± SD)

#### Procedures

All subjects wore their own training shoes and did not run on their respective testing day. The subjects started the data collection session with a 10-minute warm-up on the AG TM at 0% incline and 100% BW. This 10-minute run was intended to acclimatize the participant to the AG TM as well as to determine a speed that was associated with 75% of their estimated maximum heart rate, which would limit fatigue during the collection due to un-randomized BW conditions  $(206.9-(0.67 \text{ x age}) \times 0.75)^2$ . After the warm-up, the subject ran at the same speed throughout each of the nine testing stages (Table 3.2). Each stage lasted 3 minutes and BW percentage was decreased 5% at the end of each 3-minute stages. BW was not randomized due to a previous finding that subjects who went from reduced BW to 100% BW had higher rate of perceived exertion (RPE) and HR at the same BW conditions when compared to the group of subjects that decreased unloading.<sup>42</sup> Data collection occurred during the last 30 seconds of each stage. Subjects were asked to run normally and were asked if they were "ok" to move to the next stage prior to altering pace. The accelerometer was placed on the left leg, which was opposite of their dominant leg. The accelerometer stayed on securely for all subjects. A second testing period (n=2) was completed three weeks after the first testing period to examine the reliability of the testing protocol. All subjects completed both testing periods.

	Warm	Stage								
	up	1	2	3	4	5	6	7	8	9
BW %	100%	100%	95%	90%	85%	80%	75%	70%	65%	60%
Duration (Min)	10	3	3	3	3	3	3	3	3	3

 Table 3.2 Testing Protocol

#### Equipment

Subjects ran on the M 300 Anti-Gravity Treadmill with a Landice L8 Rehab treadmill base (Fremont, CA). Additionally subjects had a lightweight (0.7g) ceramic shear uniaxial ICP accelerometer (PCB Piezotronics, Depew, NY) mounted to the lower left tibia via a lightweight custom graphite housing chamber which was attached to a lightweight moldable plastic (Figure 3.1). The moldable plastic (InstaMorph, Scottsdale, Arizona) was heated in a microwave until it was malleable upon which was cooled enough to not harm skin but still allow for a flush fit around the tibia. Total mass of housing and accelerometer was 9.5g. In accordance with previous studies, pre-wrap tape was tightly wrapped around unit as it safely secured the unit but is not too tight to restrict natural movement.<sup>29,34,35,43</sup> Heart rate was recorded via Polar RS 300 (Lake Success, NY).

#### **Data Collection**

Accelerometer data was recorded via Qualisys Track Manager Software (Sweden) and processed with custom-written MATLAB code (Natick, MA). The manufacturer-supplied accelerometer calibration was 10.60 mV/g. Accelerometer data was collected at 1800 Hz using a Digital A/D board, DT 3002 (Measurement Computing, Norton, MA) and Qualysis Track Manager software (Sweden). Due to limitations of data collection hardware, heart rate data was not synched with accelerometer data and was collected at 5 kHz frequency.

Foot strike (FS) was observed through visual gait analysis during the last 30 seconds of each stage from both sagittal and frontal planes by the same investigator for each subject and segment. Three FS classifications were possible (Table 3.3). Foot strike was classified as either RFS, MFS, or FFS. Complete FS analysis can be viewed in Appendix F. RFS was characterized as initial contact occurring in the back third of the foot.<sup>42</sup> MFS occurs when impact is between the middle third of the foot at the proximal portion of the arch through the distal end of the arch.<sup>42</sup> FFS occurs in the distal third of the foot starting at the metatarsals through the phalanges.<sup>42</sup>



**Figure 3.1-** A uniaxial accelerometer, housed in a custom chamber and mounted to a moldable plastic cuff, was attached to the distal, anterior tibia with pre-wrap tape.

### **Data Processing & Statistical Analysis**

Accelerometer data was exported from QTM Software and processed with customwritten MATLAB code (Appendix C). The MATLAB (Natick, MA) code filtered the data with a Butterworth 4<sup>th</sup> order lowpass with a cutoff frequency of 70Hz. A graphical user interface (GUI) was created in data processing (Figure 3.3). The first two mouse clicks on the tibial acceleration versus time graph were for extracting the end segments of each trial. The next two mouse clicks established positive and negative thresholds values which aided in identification of peak values. The final two mouse clicks established a threshold for cycle time which aided peak to peak (PP) measurements (Figure 3.4).

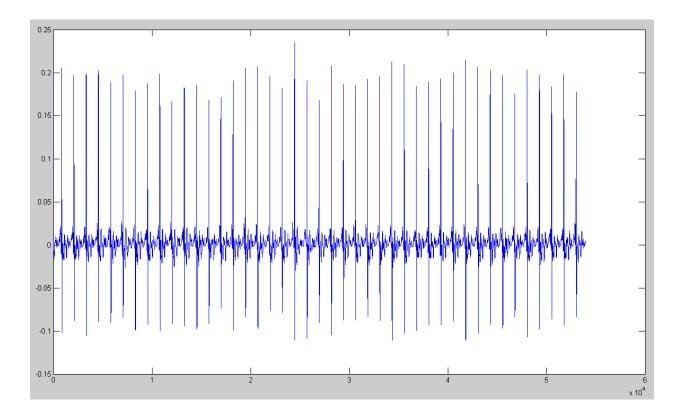
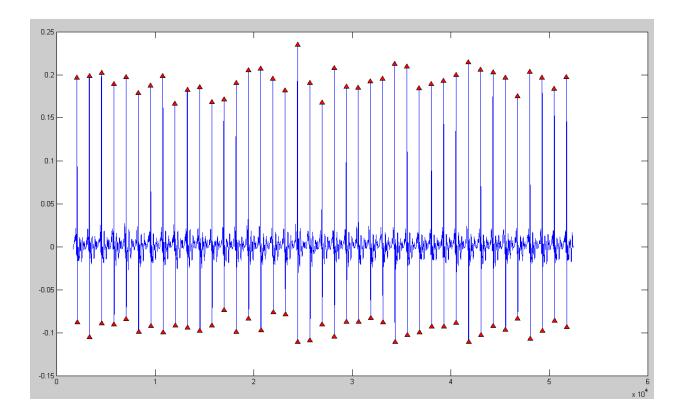


Figure 3.3- Initial filtered output from MATLAB



**Figure 3.4-** Following the six user supplied mouse clicks the peak positive and negative acceleration peaks (red triangles) were identified. Each trial was evaluated at this point to confirm the proper automatic detection of peaks.

The custom-written MATLAB script also calculated stride rate (SR) by tallying the number of positive peaks within the collection given amount of time. Each positive peak indicated left foot-floor contact. Heart rate (HR) was observed and recorded at 2:30 and 3:00 minutes of each stage and the average number observed was used as the heart rate for the stage.

Foot strike (FS) was observed by the investigator during the last 30 seconds of each stage. FS was defined in three ways as shown in Table 3.3.

 Table 3.3 Foot strike number scale

Rear	1
Mid	2
Fore	3

Data was processed using PASW (Version 16.0) (IBM Armonk, NY). A repeated measures analysis of variance (ANOVA). An RM ANOVA was used to examine differences in mean peak tibial acceleration (PTA), mean PP, mean HR, and mean SR by levels of unloading. A Bonferroni post-hoc comparison was used to test for significant differences. Significance level was set at p<0.05. Additionally, mean FS data was statistically processed using PASW (Version 16.0) (IBM Armonk, NY). A chi square analysis was applied to the FS data with a significance level set at p<0.05.

## **RESULTS**

The ANOVA revealed several significant differences between variables measured. Mean peak tibial shock at 60% BW was noticeably less than all levels of BW 70% to 95% BW, however, there was no significant (p= 0.058) difference between 60% BW and 100% BW (Table 4.1). Additionally, there was not a linear relationship between level of unloading and tibial acceleration. Mean tibial acceleration initially increased with the levels of unloading before decreasing at 70% to below 100% BW tibial shock levels. Mean tibial acceleration at 100% BW (10.58) was consistent with previous findings such as Mizrahi et al (11.1), and Derrick et al (11.3).

BW % Level	Μ	SD
60% <sup>c,d,e,f,g,h</sup>	9.75	3.28
65% <sup>d,e,f,g</sup>	10.32	3.31
70% <sup>a,d,e,f,g</sup>	10.41	3.26
75% <sup>a,b,c</sup>	10.89	3.44
80% <sup>a,b,c</sup>	11.07	3.78
85% <sup>a,b,c</sup>	11.04	3.82
90% <sup>a,b,c</sup>	11.15	3.78
95% <sup>a</sup>	10.83	3.99
100%	10.59	3.57
0' '6' 1'66 6	(001 . 00	-

 Table 4.1- Mean Peak Tibial Acceleration

a- Significant difference from 60% at p<0.05

b- Significant difference from 65% at p<0.05

c- Significant difference from 70% at p<0.05

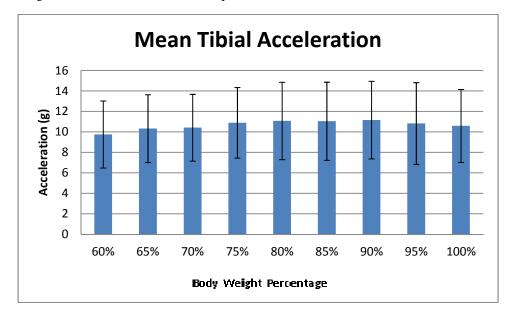
d- Significant difference from 75% at p<0.05

e- Significant difference from 80% at p<0.05

f- Significant difference from 85% at p<0.05

g- Significant difference from 90% at p<0.05

i- Significant difference from 100% at p<0.05



Graph 4.1- Mean Tibial Acceleration

Similar results were observed for PP results. An initial increase in PP was observed as BW was decreased from 100% to 85%. For all BW percentages lower than 85% PP followed a downward trend to 60% BW (Table 4.2). At 60% BW there was a significant difference observed from 100% (p= 0.021). Only 60% BW was significantly different from all other levels of unloading. At 100% BW mean PP was 18.5g's which was not consistent with previous research (13.04).<sup>29</sup>

BW % Level	Μ	SD
60% <sup>b,c,d,f,g,h,i</sup>	16.55	4.86
65% <sup>a,d,f,g</sup>	17.81	4.92
70% <sup>a,d,f,g</sup>	17.95	5.12
75% <sup>a,b,c</sup>	18.86	5.46
80%	18.04	7.78
85% <sup>a,b,c</sup>	19.18	6.09

Table 4.2- Mean Peak to Peak

90% <sup>a,b,c</sup>	19.41	6.12
95% <sup>a</sup>	18.91	6.64
100% <sup>a</sup>	18.56	5.96
a Significant differen	$r_{0}$ from 60% at $r_{0}$ 05	

a- Significant difference from 60% at p<0.05

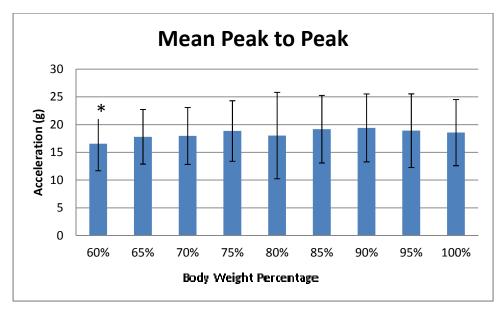
b- Significant difference from 65% at p<0.05

c- Significant difference from 70% at p<0.05

d- Significant difference from 75% at p<0.05

e- Significant difference from 80% at p<0.05

- f- Significant difference from 85% at p<0.05
- g- Significant difference from 90% at p<0.05
- h- Significant difference from 95% at p<0.05
- i- Significant difference from 100% at p<0.05



**Graph 4.2**- Mean Peak to Peak ( = significantly different from 100%)

SR decreased in a linear pattern as BW percentage was reduced, however SR did not decrease in a 1-to-1 relation to decreasing BW% (i.e 5% reduction did not result in a 5% reduction of SR). Mean SR at 100% BW was 1.45 strides per second (SPS) which was reduced

to 1.33 SPS at 60% BW. Each level of BW% when compared to the others was significantly

different from the other (Table 4.3).

BW % Level	Μ	SD
60% <sup>b,c,d,e,f,g,h,i</sup>	1.34	0.07
65% <sup>a,c,d,e,f,g,h,i</sup>	1.35	0.08
70% <sup>a,b,d,e,f,g,h,i</sup>	1.36	0.08
75% <sup>a,b,c,e,f,g,h,i</sup>	1.37	0.08
80% <sup>a,b,c,d,f,g,h,i</sup>	1.38	0.08
85% <sup>a,b,c,d,e,g,h,i</sup>	1.40	0.09
90% <sup>a,b,c,d,e,f,h,i</sup>	1.42	0.09
95% <sup>a,b,c,d,e,f,g,i</sup>	1.44	0.09
100% <sup>a,b,c,d,e,f,g,h</sup>	1.45	0.09

Table 4.3- Mean Stride Rate

a- Significant difference from 60% at p<0.05

b- Significant difference from 65% at p<0.05

c- Significant difference from 70% at p<0.05  $\,$ 

d- Significant difference from 75% at p<0.05

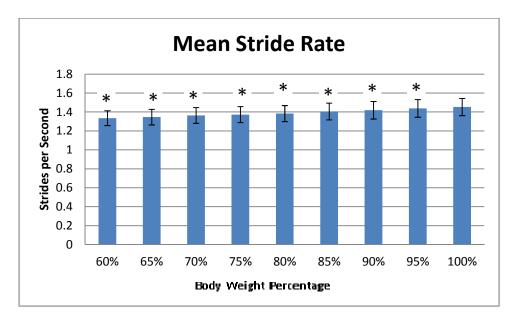
e- Significant difference from 80% at p<0.05

f- Significant difference from 85% at p<0.05

g- Significant difference from 90% at p<0.05

h- Significant difference from 95% at p<0.05

i- Significant difference from 100% at p<0.05



**Graph 4.3**- Mean Stride Rate ( = significantly different from 100%)

HR also decreased from 100% BW to 60% BW in a similar fashion as SR. Each level of unloading when compared to the others was statistically significant different from the other (Table 4.4). Mean HR was 150 (beats per minute) BPM at 100% BW and was reduced to 129 BPM at 60% BW.

BW % Level	Μ	SD
60% <sup>b,c,d,e,f,g,h,i</sup>	129.10	14.09
65% <sup>a,c,d,e,f,g,h,i</sup>	131.23	12.60
70% <sup>a,b,d,e,f,g,h,i</sup>	134.30	12.90
75% <sup>a,b,c,f,g,h,i</sup>	136.40	11.30
80% <sup>a,b,c,f,g,h,i</sup>	137.80	11.11
85% <sup>a,b,c,d,e,g,h,i</sup>	141.33	11.44
90% <sup>a,b,c,d,e,f,h,i</sup>	143.87	9.41
95% <sup>a,b,c,d,e,f,g</sup>	148.50	8.96
100% <sup>a,b,c,d,e,f,g</sup>	150.00	6.48

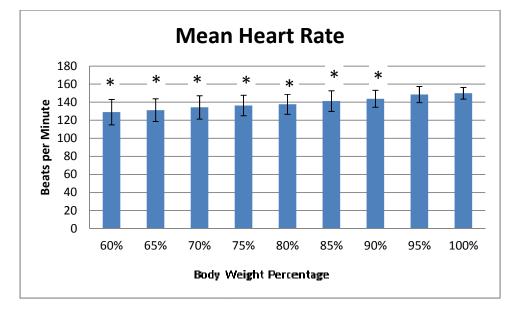
Table 4.4- Mean Heart Rate

a- Significant difference from 60% at p<0.05  $\,$ 

b- Significant difference from 65% at p<0.05

c- Significant difference from 70% at p<0.05

- d- Significant difference from 75% at p<0.05
- e- Significant difference from 80% at p<0.05
- f- Significant difference from 85% at p<0.05
- g- Significant difference from 90% at p<0.05
- h- Significant difference from 95% at p<0.05
- i- Significant difference from 100% at p<0.05

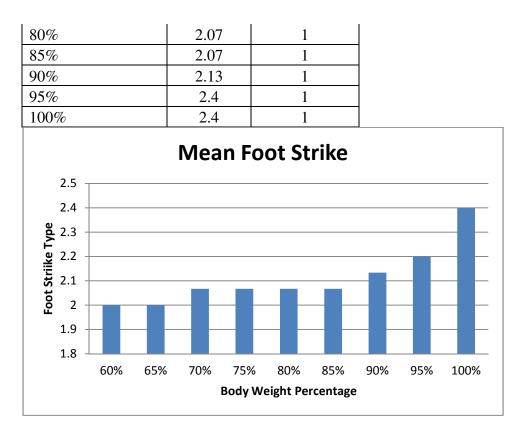


**Graph 4.4**- Mean Heart Rate ( = significantly different from 100%)

Foot strike also changed as BW% decreased. Most subjects (n= 11) were categorized as MFS at 100%. In 11 of the 15 subjects, the runner's FS changed from MFS to FFS. This was also seen in the 2 subjects who at 100% BW were RFS. There was no significant difference found do to a small cell size after running a chi squared test.

Mean Foot Strike	Μ	SD
60%	2	1
65%	2	1
70%	2.07	1
75%	2.07	1

 Table 4.5- Mean Foot Strike



Graph 4.5- Mean Foot Strike- 1= Rear, 2= Mid, 3= Fore

## DISCUSSION

The purpose of this study was to investigate the relationship between level of BW unloading and tibial acceleration. It was hypothesized that reducing BW will decrease GRF and in turn tibial acceleration. Based upon the findings of this study, is no significant link between these two variables and therefore the hypothesis is rejected. Though GRF were reduced like in other studies, there were no significant reductions in mean peak tibial acceleration in all reduced BW conditions.<sup>20,30</sup> There are multiple factors that can explain these results.

Though the overall findings of this study were different from other research, tibial acceleration results were similar when compared to other studies. Mean tibial acceleration at 100% BW (10.58) was similarly related to previous findings such as Mizrahi et al. (11.1), and Derrick et al. (11.3). From this previous research, the data collected for tibial acceleration are valid and repeatable.

Metabolic demands decreased with decrease in BW and SR which is consistent with previous findings.<sup>19,20,21</sup> Metabolic demands were assessed by HR data which decreased with unloading BW levels. This was important to note as previous research found that running while fatigued, there was an increase in ground reaction forces due to the muscles lack of shock attenuation ability.<sup>44</sup> Based off the HR data observed in this study, the subjects were not fatigued during their running intensisty.

The results of the study showed no significant difference of mean tibial acceleration from 100% BW when compared to 60% BW even though there was an overall decrease in mean tibial acceleration. There are a number of factors that could have caused these results. Unexpectedly, after the 100% BW stage, the next five stages had an increase in mean tibial acceleration. Mean tibial acceleration at 100% BW was 10.58 and increased to 10.82 (95% BW), 11.15 (90% BW), to 11.03 (85% BW), to 11.06 (80% BW), and to 10.88 (75% BW) before decreasing to below 100% BW at 70% BW (10.40).

This could have been caused by the decrease in stride rate (SR) which causes an increase in stride length (SL). These results are consistent with Hamill et al. findings in which a decreased SR from the subjects preferred stride rate decreases attenuation. The decrease in SR would result in longer ground contact time which may reduce the body's ability to dissipate and attenuate shock. This could also explain the similar results found in mean PP which also increased through the first three data collection periods (95%-85% BW) in which they were higher than 100% BW. Due to a decrease in stride rate, stride length (SL) would increase potentially creating a bouncing effect which would also explain the results in the first half of the stages.

Another factor that could have caused these results may have been the change in foot strike (FS). FS changed through the unloading stages in all subjects with the exception of two, who were both FFS from stage one. This alteration in FS could change muscle usage, which is a factor in shock attenuation. The muscles may have become fatigued from a new style of use which has shown to decrease attenutation.<sup>32,34,35,33</sup> Fatigue would have had to come from the localized muscles as the HR data, which shows statistically significant drops in heart rate as each stage decreases BW, would indicate that there was little or no metabolic fatigue among the subjects. SR and SL could have also been a factor in the change in FS.

This study controlled for terrain, which was kept at 0% grade throughout, as well as the same treadmill base. This was important for research as other research has looked into terrain

and its effects on tibial acceleration. Though important to understand to overall effects of running on all terrains, from a rehabilitation standpoint, a runner would generally avoid different terrains until they are resume normal training.

Additionally, there were other factors that alter tibial acceleration that were not controlled for. Level of BW unloading was not randomized which was assumed to be advantageous to runners based off previous research findings.<sup>37</sup> Due to a video equipment malfunction, there was no kinematic and kinetic data through video analysis to confirm FS patterns and/or body positioning alterations which also could influence tibial acceleration and ground reaction forces.<sup>6,38,40,43</sup> Lastly, foot wear type (Appendix E) was not controlled for which allowed for a variety of different materials, weight, and cushioning properties to influence ground reaction forces and their attenuation through the lower leg.

. These findings are significant for future research studies which could lead to a potential rehabilitation program. Even though mean tibial acceleration was not significant at 60% BW as compared to 100% BW, there was a modest change between the two. Additionally PP did see a significant difference between 60% and 100% BW conditions. This information is useful for those who are returning from a lower leg injury and have access to an AG TM. The injured should start 60% BW or below in order to effectively reduce stress on the lower limb. With the subject being able to participate sooner, this could speed up recovery time.

## CONCLUSION

The AG TM is a new tool in performance enhancement and rehabilitation that may have beneficial effects when it regards to tibial shock. Though this study had few significant results in mean peak tibial acceleration and mean peak to peak acceleration, it is platform to be used for future research studies and training and rehabilitation protocols. Mean peak tibial acceleration and mean peak to peak acceleration was reduced at 60% BW as compared to 100% BW which may be an ideal starting point for those who are trying to prevent running injuries or start sport specific rehabilitation sooner. With the reduction in BW, stride rate and heart rate both decrease, and foot strike changes from more rear-foot to a mid-foot strike.

## **APPENDIX** A



Sacred Heart University Consent to Act as a Research Subject

Tibial Shock in Male and Female Distance Runners in Reduced Body Weight Conditions

You are being asked to participate in a research study. Before you give your consent to volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

<u>Investigators:</u> Brendan Rickert, B.S. HFS, is a Master's student of Exercise Science and Nutrition in the Department of Physical Therapy and Human Movement Science at Sacred Heart University (SHU) and is the Principle Investigator in this study. Matthew Moran, Ph.D. is an assistant professor in the Department of Physical Therapy and Human Movement Science at (SHU) and is an Co-Investigator in this study.

#### Purpose of the Study:

Unloader treadmills have been used for clinical populations during rehabilitation for several years. These treadmills are able to 'unload' the participant such that they are able to walk or run on a treadmill at a reduced body weight (BW). Although these treadmills have been effective for gait re-training in rehabilitation settings, the manner of unloading has made them ineffective from a performance perspective. The use of differential air pressure (DAP) technology in the Alter-G (Fremont, CA) has greatly improved the method of unloading, making it far more comfortable for the athlete and thus raised the possibility for utilizing the Alter-G treadmill for reducing rehabilitation time for athletes. While walking or running on the Alter-G treadmill, the participant can manually select any level of unloading between 20-100% BW. These treadmills are now found in elite training centers across the country and many notable professional athletes are incorporating Alter-G treadmill running into their training and rehabilitation programs. Although anecdotal evidence is mounting that the Alter-G may present a new training and rehabilitation modality, limited scientific investigation has investigated the influence of varying

levels of unloading has on the running motion. If the Alter-G treadmill is to be used for rehabilitation purposes, then the effects of unloading level on tibial attenuation should be investigated. The current research proposal is designed to investigate the relationship of unloading level (100%, 95%, 90%, 85%, 80%, 75%, 70%, 65%, and 60% BW) on tibial attenuation during running in competitive male and female adult distance runners.

To participate as a subject, you must be between the ages of 18-23 years, and there must be no reason you cannot participate according to the Health History Questionnaire. You must meet all the following criterion to be considered for participation: 1) Free of any history of major medical problems including metabolic or cardiovascular disease, endocrine, thermoregulatory disorders or musculoskeletal problems, 2) have been a competitive runner for at least 3 years and 3) for a female participant, a normal menstrual cycle is required. If the female has had 3 or more consecutive missed menstrual cycles in the past 12 months, it is considered an abnormal cycle and will not be allowed to participate in the study. An exception to an abnormal menstrual cycle is if the participant is on a birth control medication that purposefully does not have a monthly menstrual cycle. This will be assessed in the Health History Questionaire.

### Procedures for this Study

You will come to the SHU Motion Analysis Laboratory (Trumbull, CT) for one data collection session that will include an explanation of all procedures; height, weight, age, and running history will be collected prior to your treadmill run. Following this you will be then run for a total of 37 minutes at a speed that is associated with 75% of your estimated maximal heart rate on the Alter-G treadmill. During this run we will alter the level of unloading between 100%, 95%, 90%, 85%, 80%, 75%, 70%, 65% and 60% of body weight.

A description of exercise testing and measurements is provided below.

Initial:

<u>Description of Measurements:</u> If you decide to participate in this study, we will collect the following measurements during your run:

• <u>Tibial Attenuation Assessment:</u> A small, lightweight accelerometer will be mounted to a lightweight moldable plastic device that will be tightly secured to your left tibia. The

device was made in order to allow for comfort, not inhibit natural motion, and allow for proper assessment of tibial attenuation. All surfaces will be smooth for the subject and there will be no pain in wearing this device.

• <u>Heart Rate</u>: You will wear a heart rate monitor during your treadmill run. The heart rate monitor is a strap that goes across your chest and transmits your current heart data to a watch.

<u>What is Experimental in this Study:</u> None of the procedures in this study are experimental in nature. The only experimental aspect of this study is the information gathered for analysis.

### Risks or Discomforts:

<u>Exercise Testing</u>: Potential risks and discomforts to you are exertional discomfort that you would commonly encounter during a sub-maximal treadmill run. Should you desire, you may stop the run at any time. In a maximal bout of exercise, there exists an approximately 2.5 in 10,000 chance of adverse symptoms with approximately a 1 in 10,000 chance of a more serious event such as a heart attack or sudden death.

<u>Responsibilities of the Participant:</u> Information you possess about your health status or previous experiences of heart-related symptoms (such as shortness of breath with activity, pain, pressure, tightness, heaviness in the chest, neck, jaw, back and/or arms) or other abnormal responses with physical effort may affect the safety of your exercise test. Your prompt reporting of these and any other unusual feelings before and during the test is of great importance. You are responsible to fully disclose your medical history, as well as symptoms that may occur during the test. You are also expected to report all medications (including non-prescription) taken recently and in particular, those taken on each day of the study, to the testing staff.

<u>Benefits of the study</u>: Potential benefits to you are an assessment of the stress you put on your tibia during running and one training session on the Alter-G treadmill. Typical Alter-G training sessions cost between \$50 and \$100.

<u>Confidentiality:</u> Records identifying you as a participant will be maintained confidential to the extent allowed by law. All results mentioned relative to your testing will be provided to you. The data will be stored in locked cabinet maintained by Dr. Matthew Moran, a professor of Sacred Heart University, until March 2017 at which time it will be destroyed.

Incentives to Participate: You will not receive any benefit from participating in this study.

<u>Voluntary Nature of Participation:</u> Participation in this study is voluntary. Your choice of whether or not to participate will not influence your future relations with Sacred Heart University. If you decide to participate, you are free to withdraw your consent and stop participation at any time without penalty or loss of benefits that you are allowed.

<u>Questions about the Study:</u> If you have any questions about the research now, please ask. If you have any questions later about research, you may contact Brendan Rickert at (203) 313-5833 or rickertb@sacredheart.edu.

<u>Consent to Participate:</u> The Sacred Heart University IRB committee has approved this consent form.

Your signature below indicates that you have read the information in this document and have had a chance to ask any questions you may have about the study. Your signature also indicates that you agree to be in the study and have been told that you can change your mind and stop your participation at any time. You have been told that by signing this consent form you are not giving up any of your legal rights.

You are making a decision whether or not to participate. Your signature indicates that you have decided to participate, having read the information provided above. You will be given a copy of this consent form to keep.

Initial: \_\_\_\_\_

### Sacred Heart University Consent to Act as a Research Subject

Tibial Shock in Male and Female Distance Runners in Reduced Body Weight Conditions

Principal Investigator: Brendan Rickert B.S. HFS

Name of Participant (please print)

Signature of Participant

Date

Signature of Investigator

\_\_\_\_\_

Date

## **APPENDIX B**

### SACRED HEART UNIVERSITY INSTITUTIONAL REVIEW BOARD

#### **APPENDIX C: EXPEDITED/FULL REVIEW FORM**

Submit (by mail or email) completed form to: Executive Secretary, IRB Office of Foundations & Grants Sacred Heart University Fairfield, CT 06825-1000 harrisv@sacredheart.edu

### PROPOSAL TITLE: <u>Tibial Shock in Male and Female Distance Runners in Reduced Body</u> <u>Weight Conditions</u>

INVESTIGATOR(S): <u>Brendan Rickert, BS HFS (PI), Matthew Moran, Ph.D.</u> DEPARTMENT: <u>Physical Therapy & Human Movement Science</u> FACULTY \_ STUDENT\_X\_\_\_\_ ADDRESS: <u>Brendan Rickert, 805 Briarwood Ave, Bridgeport, CT 06604</u> EMAIL ADDRESS: <u>rickert@sacredheart.edu</u> TELEPHONE NUMBER: (203)313-5833 (cell) FACULTY ADVISOR (if student): <u>Dr. Matthew Moran</u>

TYPE OF REVIEW REQUESTED: FULL\_\_\_\_\_ EXPEDITED\_\_X\_\_\_

IF EXPEDITED REVIEW, indicate the section(s) in 6.2 of the IRB Guide under which this proposal qualifies for expedited review: \_\_\_\_\_ 6.2.1 & 6.2.2 \_\_\_\_\_

FULL OR EXPEDITED REVIEW, check the appropriate response:

\_\_\_\_YES \_\_X\_\_NO The protocol involves human subjects who will receive drugs.

\_\_\_\_YES \_\_X\_\_NO The protocol involves human subjects who will receive or be exposed to radioactive materials.

\_\_\_\_YES \_\_X\_NO The protocol involves human subjects and will take place in an outside facility.

The protocol involves human subjects who are: \_\_\_\_minors (under age 18), \_\_\_fetuses, \_\_\_\_pregnant women, \_\_\_\_prisoners, \_\_\_\_mentally retarded, \_\_\_\_mentally disabled.

The protocol is being submitted for \_\_\_\_\_ Federal funding, \_\_\_\_Other external funding.

The investigator must provide summary statements addressing the following points of information. Where indicated, include the protocol page number(s) that contains detailed information. Use supplemental pages if necessary.

#### PURPOSE OF THE STUDY:

Unloader treadmills have been used for clinical populations during rehabilitation for several years. These treadmills are able to 'unload' the participant such that they are able to walk or run on a treadmill at a reduced body weight (BW). Although these treadmills have been effective for gait re-training in rehabilitation settings, the manner of unloading has made them ineffective from a performance perspective. The use of differential air pressure (DAP) technology in the Alter-G (Fremont, CA) has greatly improved the method of unloading, making it far more comfortable for the athlete and thus raised the possibility for utilizing the Alter-G treadmill for reducing rehabilitation time for athletes. (Flynn et al. 1997) While walking or running on the Alter-G treadmill, the participant can manually select any level of unloading between 20-100% BW. These treadmills are now found in elite training centers across the country and many notable professional athletes are incorporating Alter-G treadmill running into their training and rehabilitation programs. Although anecdotal evidence is mounting that the Alter-G may present a new training and rehabilitation modality, limited scientific investigation has investigated the influence of varying levels of unloading has on the running motion. If the Alter-G treadmill is to be used for rehabilitation purposes, then the effects of unloading level on tibial attenuation should be investigated. Tibial attenuation has been measured in other studies to help better understand the relationship between typical forces experienced during running and implications for tibial stress fracture occurrences. (Liebenberg et al. 2010) Tibial stress fractures are the most common types of stress fractures among competitive runners in both males and females. Females typically have higher rates of stress fractures; however, this increase can be partially attributed to nutritional deficiencies and abnormal menstrual cycles. (Milner et al. 2006) The current research proposal is designed to investigate the relationship of unloading level (100%, 95%, 90%, 85%, 80%, 75%, 70%, 65%, and 60% BW) on tibial attenuation during running in competitive male and female adult distance runners.

CHARACTERSITIC OF SUBJECT POPULATION: Include selection criteria and any age, sex, physical, mental and health restrictions.

To participate as a subject, each participant must be between the ages of 18-23 years of age, and there must be no reason they cannot participate according to the Health History Questionnaire. The study will include male and female subjects. Each participant must meet the entire following criterion to be considered for participation: 1) Free of any history of major medical problems including metabolic or cardiovascular disease, endocrine, thermoregulatory disorders or musculoskeletal problems, 2) have been a competitive runner for at least 3 years and 3) for a female participant, a normal menstrual cycle is required. If the female has had 3 or more

consecutive missed menstrual cycles in the past 12 months, it is considered an abnormal cycle and will not be allowed to participate in the study. An exception to an abnormal menstrual cycle is if the participant is on a birth control medication that purposefully does not have a monthly menstrual cycle. This will be assessed in the Health History Questionnaire. Subjects will be recruited from Sacred Heart University's cross-country team. Based on pilot data and previous research, 15 subjects will be recruited for this experiment.

#### METHODS AND PROCEDURES APPLIED TO HUMAN SUBJECTS:

Prior to participation in this study, all subjects will complete a short Health History Questionnaire and will only be allowed to participate in the study if they do not have any contraindications to exercise or the procedures used in this study. Additionally all participants will be active members on the men's and women's cross country team at Sacred Heart University and have undergone medical clearance to participate on this team.

Subjects will complete one 37-minute sub-maximal run on the Alter-G (Fremont, CA) treadmill located in the Motion Analysis Laboratory (Oakview Campus, Sacred Heart University). The subjects will begin with a 10-minute warm-up run on the Alter-G in order to familiarize them to the treadmill as well as find a speed that will elicit 75% of their estimated maximum heart rate. Maximum heart rate will be assessed by using the following formula, endorsed by the American College of Sports Medicine: 206.9- (.67 x age). The run will be portioned into nine continuous 3-minute segments at 100%, 95%, 90%, 85%, 80%, 75%, 70%, 65% and 60% of body weight. The ordering of these levels of unloading will start at 100% and work down to 60% due to the fatigue related factors of increasing loading during the run. In addition to measuring tibial attenuation, heart rate will be measured twice during each stage at 2:30 and 3 minutes.

In order to assess tibial attenuation, a lightweight (0.7g) ceramic shear ICP accelerometer (PCB Piezotronics, Depew, NY) will be mounted to the lower left tibia. The mounting device is made up of a lightweight moldable plastic that will fit flush with the bony structure of the tibia. Due to the moldable plastic, the mounting device will cause no discomfort and is safe for the subject. The plastic is non-toxic. The accelerometer will rest in a light-weight plastic anchor and then screwed into the plastic device. The unit in total weighs 2.2g and is formatted so that the device fits flush with the skin. This device mimics previous devices that have been used in other studies due to its lightweight design and has shown to not inhibit natural activity.

RISKS TO THE SUBJECT: <u>X</u>YES <u>NO</u> If subjects will be at risk, assess the probability, severity, potential duration and reversibility of each risk. Indicate protective measures to be utilized.

None of the procedures in this study are experimental to the participants. All risks for the study have been minimized. Risks and discomforts to the participants are normal exertional discomfort experienced during sub-maximal treadmill runs.

In a maximal bout of exercise, there exists an approximately 2.5 in 10,000 chance of adverse symptoms with approximately a 1 in 10,000 chance of a more serious event such as a heart attack or sudden death. Since this is a sub-maximal run, the odds of an adverse event are lower.

All testing will be sub-maximal and will be scheduled during normal university business hours when the Sacred Heart University Department of Public Safety (DPS) is available for immediate assistance if required. The Automated External Defibrillator (AED) in the Oakview Campus is located directly outside the door of the Motion Analysis Lab. All testing will be in the presence of a professional trained in CPR.

BENEFITS: \_\_X\_YES \_\_\_NO Describe any potential benefits to be gained by the subject as well as benefits that may accrue to society in general.

The subject will receive minimal training benefits from this study. A typical training session on an Alter-G treadmill cost between \$50-100.

INFORMATION PURPOSELY WITHHELD: \_\_\_\_YES <u>X</u>NO State any information purposely withheld from the subject and justify this non-disclosure.

CONFIDENTIALITY: Describe how confidentiality of data will be maintained.

Confidentiality will be maintained by assigning each participant a code number and recording all data by that code. Brendan Rickert will keep the only record with the subject's name and code number in a locked desk at Sacred Heart University (Motion Analysis Laboratory). No name, initials, or other indentifying characteristics will be reported in the publication of the data obtained. Data will be stored by Dr. Matthew Moran for a period of 5 years and then be destroyed no later than March 2017.

Bund Mihit

2/23/12

DATE

SIGNATURE OF PRINCIPAL INVESTIGATOR\*

Masters Student POSITION \*Signature certifies that the investigator to the best of his/her knowledge is in full compliance with the federal and Sacred Heart University regulations governing human subjects research.

#### ATTACHMENTS, for example

- 1. Informed Consent Form(s) (required, unless waiver is requested)
- 2. Detailed Research Protocol (see Appendix D)
- 3. Questionnaires or Test Instruments
- 4. Requests for approval from outside facilities
- 5. Federal forms, if applicable

FOR IRB USE ONLY

ACTION TAKEN: \_\_\_\_\_\_ DATE: \_\_\_\_\_\_ SIGNATURE: \_\_\_\_\_\_ IRB CHAIRPERSON

(Revised August, 2005)

# **APPENDIX C**



**Health History Form** 

Please indicate whether any of the following apply to you. If so, please place a check in the blank beside the appropriate item. Thank you.

\_\_\_\_\_ Hypertension or high blood pressure

\_\_\_\_\_ A personal OR family history of heart problems or heart disease

\_\_\_\_\_ Diabetes

Orthopedic	problems
 orthopeare	problems

\_\_\_\_\_ Cigarette smoking or other regular use of tobacco products

\_\_\_\_\_ Asthma or other chronic respiratory problems

\_\_\_\_\_ Recent illness, fever or Gastrointestinal Disturbances (diarrhea, nausea, vomiting)

Last Menstrual Cycle\_\_\_\_\_ Have you missed 3 or more consecutive menstrual cycle in the past 12 months? \_\_\_\_\_\_

\_\_\_\_\_Birth Control\_\_\_\_\_\_ Does taking this medication interfere with monthly menstrual cycles?

\_\_\_\_\_ Any other medical or health problems not listed above (provide details below):

I certify that my responses to the questions above are true, accurate, and complete.

Signature:\_\_\_\_\_ Name (printed):\_\_\_\_\_

Legal Guardian (if under 18 yrs. of age): \_\_\_\_\_

Date: \_\_\_\_\_

## APPENDIX D



### SACRED HEART UNIVERSITY Institutional Review Board (IRB)

for Research Involving Human Subjects

**DATE:** March 2, 2012

TO: Name		Brendan Rickert, BS HFS (PI), Matthew Moran, Ph.D.		
	Address	Physical Therapy & Human Movement Science		
	Telephone	203-313-5833		

FR: Name/Title Dr. Stephen Lilley

Address Sociology Department

**Telephone** 203-371-7761

**RE: Proposal** Tibial Shock in Male and Female Distance Runners in Reduced Body Weight Conditions

- \_\_X The IRB has reviewed and approved the above-referenced proposed project. Please honor the following requirements when conducting your study:
  - > At all times, minimize risks to subjects.
  - Any significant change in procedure that may impact subjects must first be approved by the IRB.
  - Insure adequate safeguarding of sensitive data during the study, and destroy sensitive material when the study is completed.

> If the study continues beyond one year, an annual review form must be filed with the

IRB.

If results are disclosed to subjects, agencies, etc., make sure that the findings are disclosed in such a manner that confidentiality is protected.

# **APPENDIX E**

## SUBJECT TESTING DATA

Subject	<b>Running Velocities</b>	Footwear Type	Foot Strike Pre	Foot Strike Post	
1	7.6	Cushioning	Rear	Mid	
2	7.6	Cushioning	Mid	Mid/	
3	8.1	Racing Flat	Fore	Fore	
4	8.4	Neutral	Mid	/ Fore	
5	8.5	Motion Control	Mid	Mid	
6	7.3	Neutral	Rear	/ Fore	
7	8.1	Cushioning	Mid	/ Fore	
8	6.9	Cushioning	Mid	Mid	
9	8.3	Neutral	Mid	Fore	
10	7.9	Racing Flat	Fore	Fore	
11	7.1	Stability	Mid	Fore	
12	7.9	Neutral	Mid	Fore	
13	8.6	Racing Flat	Mid	/ Fore	
14	8.5	Racing Flat	Fore	Fore	
15	7.9	Stability	Mid	Mid/	

# **APPENDIX F**

## SUBJECT FOOT STRIKE DATA

Subject	100%	95	90	85	80	75	70	65	60
1	1	1	1	1	1	2	2	2	2
2	2	2	2	2	2	2	2	2	2
3	2	2	2	2	2	2	2	2	3
4	2	2	2	2	2	2	2	2	2
5	2	2	2	2	2	2	2	2	2
6	1	1	2	2	2	2	2	2	2
7	2	2	2	2	2	2	2	2	2
8	2	2	2	2	2	2	2	2	2
9	2	2	2	2	2	2	2	3	3
10	3	3	3	3	3	3	3	3	3
11	2	2	2	2	2	1	2	2	3
12	2	2	2	2	2	2	2	2	3
13	2	2	2	2	2	2	2	2	2
14	3	3	3	3	3	3	3	3	3
15	2	2	2	2	2	2	2	2	2

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