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Influence of Compression Socks on Unilateral Balance in Females

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The University of Southern Mississippi

Influence of Compression Socks on Unilateral Balance in Females

by

Alex Carlson

A Thesis
Submitted to the Honors College of
The University of Southern Mississippi
in Partial Fulfillment
of the Requirement for the Degree of
Bachelor of Science
in the Department of Kinesiology

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Abstract

The application of compression garments for various purposes has become popular in recent years. Research regarding the effectiveness of these garments has shown an increase in variables such as increased blood flow, decreased post-exercise soreness, and increased joint position awareness. However, little research is available concerning their possible use to increase joint stability. This research examined the efficacy of graduated compression stockings (GCS) to increase proprioceptive feedback from the ankle joint. It was hypothesized that continuous stimulation of sensory receptors in the ankle region by use of GCS would improve an individual's static unilateral balance. Seventeen females (age: 20 +/- 1.118) without previous ankle, knee, or hip injury in their dominant leg were selected for participation in the study. For each subject, there were eyes-opened versus eyes-closed, sock versus no-sock, and immovable platform versus movable platform conditions. Using a Balance System SD, subjects' unilateral balance was measured for each of the eight testing condition combinations. No statistically significant differences were found between the conditions.

Key Words: Proprioception, compression garment, balance

Dedication

To my God: For Your glory alone

To my family: For always helping me press on toward my goals

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1. Introduction

Balance can be defined as the body's ability to preserve its center of mass over its support base. It is maintained and affected by three major sensorimotor systems: somatic, visual, and vestibular (Shumway-Cook & Woollacott, 2001). The somatic system is associated with the vast variety of afferent or sensory neurons and the information they provide to the central nervous system (CNS) related to muscular movement and joint positioning. The visual system is associated with sensory feedback provided to the CNS via eyesight. The vestibular system is associated with sensory feedback to the CNS provided by the fluid-filled and cilia-lined semicircular canals within the inner ear. These systems functionally "work together" to form a higher-order neural network which allows the highly functional task of balance and ambulation. Among these three systems, the somatic system was the focus of this intervention. Proprioception is the capability of the CNS to identify, through neural feedback from the skin, muscles and connective tissue, where in space a particular joint or limb is located at any given time. Proprioception is a function of the somatic system (Bottoni, Herten, Kofler, Hasler, & Nachbauer, 2013). It is well understood that alterations to individual sensory components associated with the somatic system can influence an individual's proprioceptive abilities (Tropp, 2002).

Because the dermis (skin) is filled with free nerve endings and afferent receptors, and it is a part of the somatic system, it has been hypothesized, within the ankle injury prevention literature related to external bracing, that continuous stimulation to areas of the body, like the ankle joint could potentially improve a person's overall balance. Work found within the scientific body of literature suggests that tight fitting compression

garments (CGs) could provide the necessary stimulus to enhance proprioceptive feedback (Michael, Dogramaci, Steel, Graham, 2014). Due to the flexible, elastic nature of CGs, an individual's static unilateral balance could be improved without sacrificing the joint's range of motion (as is a concern with more robust external ankle supports). To support such claims, research has shown that CGs applied to certain areas of the body, have a positive effect on joint proprioception (Kraemer et al., 1996; Pearce, Kidgell, Grikepelis, & Carlson, 2009). In studying CGs such as shorts or pants, the proprioceptors at the hip, knee, and ankle joints are all directly influenced by the CG. To date, little has been done to evaluate if this same effect can be elucidated at other joints, like the ankle. Recently, an identifiable trend of athletes donning full-length compression socks has been observed. With previous research establishing that the ankle is the primary joint for corrective action in a unilateral stance in college students (Riemann, Myers, & Lephart, 2003) it is clear that action towards investigating proprioceptive effects of CG, namely full-length socks at the ankle, is merited.

Therefore the purpose of this study was to observe and measure the effect of compression socks at the ankle joint on proprioception and to measure their influence on unilateral balance. It was hypothesized that when comparing the effect of continuously stimulating sensory receptors in the ankle region, the use of compression socks would have a positive affect on a person's static unilateral balance as measured by the Biodex Balance System SD. Overall, it was considered that the findings of this study could alter the way coaches, athletes, physical therapists, and physicians use and prescribe prophylactic compression socks.

2. Literature Review

2.1 Compression Garments

There are three different types of CGs: pants or shirts typically worn during exercise, sleeves often worn over limbs to aid in the reduction of swelling, and stockings worn to treat or prevent deep vein thrombosis (Barnett, 2006). The effectiveness of CGs during exercise has been researched, and some suggested that CGs aid in submaximal intensities in the following physiological areas: reduction of muscle oscillation, increased awareness of joint position, increased blood flow, and improved oxygen use (MacRae, Cotter, & Laing, 2011). When used for the alleviation of swelling and inflammation due to lymphedema – an incurable condition that often occurs in individual's who have recently undergone axillary node surgery, the rationale behind the success was unknown (Brennan & Miller, 1998; Gergich, Pfalzer, McGarvey, Springer, Gerber, & Soballe, 2008). CGs are often prescribed for postoperative patients as a prophylaxis for deep vein thrombosis as well (Geerts, Pineo, Heit, Bergqvist, Lassen, Colwell, & Ray, 2004). CGs have also been used effectively to reduce the amount of delayed onset muscle soreness (DOMS) after bouts of maximal level exercise (Duffield and Portus, 2007). Likewise, the removal of blood lactate after maximal level exercise seems to be affected by use of CGs (Bottaro, Martorelli, & Vilaca, 2011). However, the understanding behind these successes is still unknown. Although there exists an abundance of research regarding the success or failure of CGs for various physiological and vascular aspects of the body, research regarding the effect of CGs on proprioception and balance is scarce.

2.2 Pressures

An evaluation of graduated compression stockings (GCS) was done for a sample of females to assess the pressure distribution on the skin due to the stockings. This evaluation used the FlexiForce interface pressure sensor (Tekscan, Inc., Boston MA, USA) to measure the skin pressures at various locations on the lower limb. Pressures were highest at the ankle region and followed a gradient of decreasing pressures toward the upper part of the leg. Ankle pressures specified by the manufacturers and suggested functions were as follows: 10-16 mmHg to prevent varicose veins and relieve heaviness and fatigue, 18-25 mmHg to cure mild varicosities, aching, and swelling, 25-32 mmHg to cure moderate varicose veins, edema, and mild chronic venous insufficiency, 30-40 mmHg to cure serious varicose veins, severe edema, lymphedema, and leg ulcers. The study found that the pressures measured at the ankle region for each GCS was not equal to the pressure indicated by the manufacturers. These findings assert that the pressures at which manufacturers state are useful to accomplish certain goals may or may not be the actual pressures at which these goals can be accomplished (Liu, Kwok, Li, Lao, Zhang, & Dai, 2005). A similar assessment was done a few years later by the same researchers. This evaluation also involved a minimum ankle pressure of 10 mmHg, but a maximum pressure of 46.5 mmHg. Uses of the GCS at each pressure range as stated by the manufacturers were similar to those of the first study. This second study found that subjects with occupations requiring being seated for long periods of time would benefit more from light-pressure GCS (10-14 mmHg), while subjects within a clinical setting would profit more with use of mild-pressure GCS (18.4-21.2 mmHg) (Liu, Lao, Kwok, Li, & Ying, 2008). Based on these two studies and their relevancy to the current study,

regardless of pressures at which manufacturers state to be beneficial, a GCS pressure range of 10-14 mmHg will suffice to activate skin-level proprioceptors.

A study examining the influence of GCS on various physiological and perceptual responses during and post-exercise was done for a sample population of fourteen males. Each participant's legs were fitted for his own GCS. The GCS used were knee-length and commercially available (Venosan, 4001, St. Galen, Switzerland). The stockings offered graduated compression with the highest pressure being at the ankle and declining by 70% at the uppermost part of the stocking. The pressure given at the ankle was 18-22 mmHg. Though there were no significant findings of the physiological effectiveness of the GCS, there were heightened perceptual sensations (Ali, Caine, & Snow, 2007). This indicates that GCS could successfully apply appropriate pressures to enhance the proprioceptive awareness of subjects. Generally, the minimal pressure at the ankle region for commercially offered GCS is approximately 10 mmHg. For the current study, the CG was used with only the intent of stimulating skin level proprioceptors. The pressure provided by the CG was 25 mmHg at the ankle region and diminished to a pressure of 18 mmHg toward the calf region.

2.3 Proprioception

Various studies have been done to measure the effect of CGs on balance. A study of this nature was performed for healthy, college-age females wearing compression shorts. This study included the following six unilateral balance tests: eyes opened while wearing standard exercise shorts, loose-fitting compression shorts, then fitted compression shorts and the same three trials with eyes closed. These tests considered

both the visual and somatic systems of balance with proprioceptive feedback from the hip joint downward to the ankle joint. The results showed that well-fitted CGs were more beneficial to maintaining a unilateral stance than were traditional exercise shorts. Results also suggested that well-fitted CGs could be beneficial to physically active individuals for improving balance and reducing the likelihood of injury (Michael et al., 2014). While similar to the research setup of the current investigation, this study measured the effects of both the visual and somatic systems of balance. With this double variable, there is a level of uncertainty as to which system most affected the subjects' balance.

The effect of CGs on college volleyball players' power during a vertical jump was measured for a sample of both men and women; this study also experimented with compression shorts. Its results indicated that compression shorts were beneficial to the subjects' maintenance of power throughout repeated vertical jumps. However, the CGs had no influence on the volleyball players' power during a single maximal effort vertical jump. Furthermore, the results suggested that the compression shorts could have enhanced the proprioceptive feedback and therefore enhanced the power during repetitive jumps (Kraemer et al., 1996).

In a study concerning the efficacy of neoprene shorts on joint position awareness in elite Australian Football players, players carried out forty movements without visual aid while wearing loose-fitting shorts. Their movement discrimination (MD) score was calculated, and they were placed in groups of either low or high neuromuscular control capabilities. The subjects completed the same test wearing the neoprene shorts. The MD scores of the lower ability group increased, while the MD scores of the higher ability group decreased (Cameron, Adams, & Maher, 2008). This suggests that proprioceptive

abilities in injured or lower neuromuscular controlled individuals is more likely to be enhanced by use of CGs.

Taking into consideration the inconsistencies and scarcity of literature regarding female subjects and proprioception, the present study sought to measure the influence that a particular compression sock has on proprioceptors at the ankle joint of females. It served as a preliminary study in determining the effectiveness of this type of prophylactic ankle support in enhance static unilateral balance.

3. Methodology

3.1. Participants

Based up convenience, this study was limited to include healthy, college-aged female subjects. The University of Southern Mississippi's Institutional Review Board approved all recruitment and experimental procedures. Oral announcements were made on the campus of the University. Individuals interested in the study were given general medical questionnaires created by the researcher in order to determine each participant's eligibility in the study. Possible participants were asked if they engaged in regular physical activity (at least thirty minutes per day for a minimum of 5 days per week). They were also asked if they have ever or are currently engaged in organized gymnastics, tumbling, cheerleading, or dance. They were asked with which leg they would kick a soccer ball in order to determine their dominant leg. Individuals with previous ankle, knee, or hip injuries in their dominant leg were excluded from participation in the study as their balance might have already been altered. Individuals with any diagnosed vestibular disorders, vertigo, balance disorders, or allergies to latex were excluded from the study. Finally, they were asked if they require any type of corrective vision wear such as glasses or contacts that would need to be worn throughout testing. After each of the potential participants completed the medical questionnaire, the researcher analyzed the surveys.

A sample of 17 female university students aged 20 ± 1.118 was selected for participation in the study. Fourteen of the participants had a dominant right foot, while three had a dominant left foot. The participants had a height range of 63.412 ± 3.242

inches. The research was carried out using a within-subjects experimental design in a laboratory setting. Subjects were asked to attend two 30-minute testing periods of their choosing – one per day for two consecutive days.

3.2. Procedures

The testing was done using a Biodex Medical Systems instrument – the Balance System SD. This instrument has capabilities to measure static and dynamic balance, “SD”, in both bilateral and unilateral stances (Biodex, 2015). For the purposes of this study, the balance system was used to measure static balance in a unilateral stance at two different platform settings. For the sake of eliminating as much error as possible a simple compression sock was chosen to serve its purpose only to continuously stimulate skin-level proprioceptors. Any added stabilization mechanisms – such as bars or posts – could have created an unwanted benefit to the subjects’ balance. A highly popular brand of readily available compression socks were chosen. Multiple pairs of socks –sized extra small, small, and large were donated by the company for the stud. In order to eliminate the assistance of the visual system to their balance, half of the measurements were to be done with eyes opened and half with eyes closed. Subjects were barefoot to eliminate assistance or hindrance from footwear.

Participants were tested at separate appointment times. As each participant entered the testing room on the first day, she was debriefed and asked to read and sign the informed consent. Participants were asked to remove any footwear and were given further information as to what was to be expected of them and the researcher throughout the testing process. The researcher programmed the balance system to fit each

individual. Subjects were asked not to speak throughout each testing condition; the researcher did not speak as well. They were given two 10-second practice trials – one with a static platform and one with a movable platform – in order to familiarize them with the balance system.

Each individual's unilateral balance on her dominant leg was measured and recorded for eight separate measurements. Each of the eight measurements consisted of three 30-second trials with a 10-second rest period between each trial. Four of the measurements were done using the balance system with a static platform set at 1. The measurements were as follows: one in which the subject did not wear the compression sock with eyes opened, one in which she did wear the compression sock with eyes opened, and the same two measurements were done with the subject's eyes closed. The same four measurements listed above for a static platform were also done on a moveable platform set at 6. Testing order was randomized for each participant.

In the interest of not fatiguing the subjects' ankles between measurements, 1-2 minutes of rest time between each measurement was given. For each condition, they were allowed to stretch and/or sit in a provided chair until it was time for the next measurement to begin. Following the testing period, a brief subjective analysis was done in order to determine the individuals' perception of the effectiveness or inadequacy of the compression socks in enhancing proprioception, joint stability, and/or overall balance.

3.3. Illustrations



Illustration 1: Biodex Balance System SD
Unilateral



Illustration 2: Dominant Leg
Stance on the Biodex System



Illustration 3: Biodex Balance System
Viewing Screen

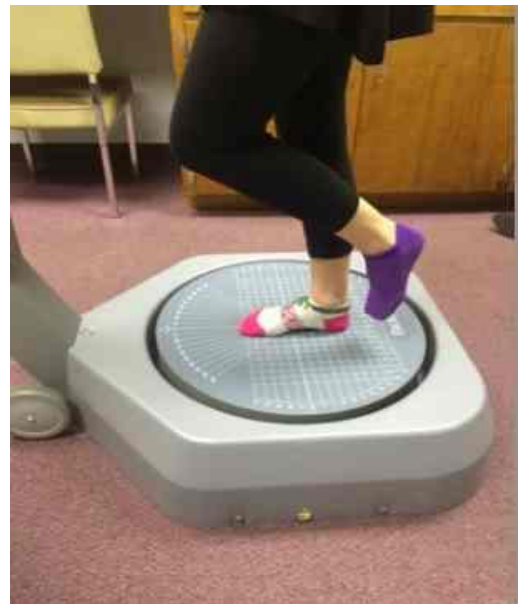


Illustration 4: Unilateral Stance on
Unmoving Platform



Illustration 5: Biodex System Viewing



Illustration 6: Dominant Leg

Screen Close Up

Unilateral Stance (Eyes Opened)



Illustration 7: Dominant Leg Unilateral

Stance (Eyes Close)



Illustration 8: ShockDoctor®

Compression Socks

4. Results

Data was analyzed using a t-test to evaluate differences in stability indices, anterior/posterior movement, and mediolateral movement between each pair of conditions in terms of no sock versus sock. The mean stability indices, standard deviations, and standard error mean for all no-sock/sock pairs with eyes opened are presented in **Table 1** below. Differences in these stability indices are presented in **Table 2** with each value's standard deviation, standard mean error, confidence interval, t-value, degrees of freedom ($n - 1=16$), p-value, and Cohen's d. Positive mean differences indicate an improvement in scores from control (no sock) to treatment (sock) conditions; while negative values indicate the opposite. No statistically significant differences were found between the control and treatment groups for the sample ($n=17$). The mean stability indices, standard deviations, and standard error means for all sock/no- sock pairs with eyes closed are presented in **Table 3** below. Any differences in the mean stability indices are presented in **Table 4** with each figure's standard deviation, standard error mean, confidence interval, t-value, degrees of freedom, p-value, and Cohen's d. Again, positive values indicate improvement and negative values indicate decline. No statistically significant differences were found between the control and treatment groups for the sample ($n=17$). The null hypothesis failed to be rejected.

Table 1. Sample Statistics for Eyes Opened Conditions

		Mean	Std. Dev.	Std. Error Mean	Significance (2- tailed)
--	--	------	-----------	--------------------	-----------------------------

AB	eyes open no sock					
	1 SI - eyes open sock 1 SI	.0471	Mean 4529	Std. Deviation		Std. Error Mean
CDA	eyes open no sock 1 AP - eyes open sock 1 SI	.0412	.929 .4258	.5924 .1033		.1437 .695
B	eyes open no sock sock 1 AP sock 1 SI		.882	.4876		.1183
EFC	eyes open no sock 1 ML - eyes open sock 1 SI	-.0647	.647 .2668	.4529 .0647		.1099 .332
D	eyes open no sock sock 1 ML sock 1 AP		.606	.3648		.0885
GHE	eyes open no sock 6 SI - eyes open sock 1 SI	.0647	.494 1.9758	.2164 .4792		.0525 .894
F	eyes open no sock sock 6 SI sock 1 ML		.559	.3906		.0947
IJ G	eyes open no sock 6 AP - eyes open sock 6 SI	.0765	3.353 1.0762	1.8745 .2610		.4546 .773
H	eyes open no sock sock 6 AP sock 6 SI		3.288	1.9036		.4617
KLI	eyes open no sock 6 ML - eyes open sock 6 SI	-.0529	1.706 2.0150	1.4665 .4887		.3557 .915
J	eyes open no sock sock 6 ML sock 6 AP		1.629	.9081		.2203
K	eyes open no sock ML		2.676	1.4788		.3587
L	eyes open no sock sock 6 ML		2.729	1.8278		.4433

Table 2. Paired Sample Differences for Eyes Opened Conditions

		Mean	Std. Deviation	Std. Error Mean
A	eyes closed no sock 1	2.718	.7418	.1799
B	eyes closed sock 1 SI	2.924	.8482	.2057
C	eyes closed no sock 1 ap	1.924	.6515	.1580
D	eyes closed sock 1 AP	1.988	.6061	.1470
E	eyes closed no sock 1 ML	1.588	.5743	.1393
F	eyes closed sock 1 ML	1.765	.7314	.1774
G	eyes closed no sock 6 SI	6.888	2.6706	.6477
H	eyes closed sock 6 SI	6.535	2.2913	.5557
I	eyes closed no sock 6 AP	4.365	1.7135	.4156
J	eyes closed sock 6 AP	4.565	1.7628	.4275
K	eyes closed no sock 6 ML	4.524	2.5059	.6078
L	eyes closed sock 6 ML	3.971	1.7463	.4235

Table 3. Paired Sample Statistics for Eyes Closed

		Mean	Std. Deviation	Std. Error Mean	Significance (2-tailed)
	eyes closed no sock 1 - eyes closed sock 1 SI	-.2059	.9202	.2232	.370
	eyes closed no sock 1 ap - eyes closed sock 1 AP	-.0647	.8507	.2063	.758
	eyes closed no sock 1 ML - eyes closed sock 1 ML	-.1765	.5345	.1296	.192
	eyes closed no sock 6 SI - eyes closed sock 6 SI	.3529	2.0764	.5036	.493
	eyes closed no sock 6 AP - eyes closed sock 6 AP	-.2000	1.5945	.3867	.612
	eyes closed no sock 6 ML - eyes closed sock 6 ML	.5529	2.3511	.5702	.347

Table 4. Paired Sample Differences for Eyes Closed Conditions

5. Discussion

The aim of this study was to investigate the efficacy of full-length compression socks on a task of static, unilateral balance in healthy college-aged females to improve overall task performance in balance. It was hypothesized that the addition of the compression socks would produce an improved stability index due to increased proprioceptive feedback. Previous work reported in the literature provided support for the hypothesis (Steinberg, Waddington, Adams, Karin, & Tirosh, 2016). However, our study found no statistically significant differences found between the experimental values from no-sock to sock conditions.

5.1. Stability Indices

Comparison of observed means (overall stability indices across all directions) for each pair of conditions, both eyes-opened conditions showed diminutive differences between control and treatment groups. It is postulated that the stimulus to exacerbate static balance, platform settings (1-immovable-12 highly moveable) were set too low to result in a more meaningful stimulation of the dermal proprioceptors.

5.2. Limitations

With a sample size of $n=17$, the study was limited by the amount of participants, and therefore the possibilities of seeing a change between the control and treatment groups. A future study should include a larger sample. Although there was no statistically significant difference between the sock and no sock groups, there were small

observed differences amongst the mean values that were directionally meaningful. Based upon moderate measure of effect size around each variable, it is postulated that a more robust sample size could have resulted in significant findings. It can be inferred that with a larger sample size, a positive change from control to treatment groups would be seen. A second limitation is the duration of each trial condition. In this study, for each of the eight conditions, participants stood unilaterally for three 30-second trials. Subsequent studies investigating the efficacy of compression socks for balance should involve more rigorous interventions than did the current study. That is to say, they should include trials longer in duration than 30 seconds each. Extended trials would offer more time to stimulate ankle proprioceptors as the primary system of balance. For the four moveable platform conditions, the balance system was set to an instability level of 6. Future studies could raise the difficulty of each moveable platform condition by increasing the platform's instability to level 12. This increase in duration and difficulty would evoke a proprioceptive response to maintain the individuals' balance. Their proprioceptive systems would be further exacerbated in the four eyes-closed conditions.

6. Conclusion

For the present study, it was determined that a more robust protocol is needed in order to isolate the proprioceptive system of balance in subjects' unilateral balance. Furthermore, no statistically significant differences were found between the control and treatment groups. Hence, the protocol for the conditions was not sufficient to promote the proprioceptive system of balance over the other two systems, or the conditions' duration was not long enough to emphasize possible benefits of the compression socks.

However, observable differences allowed for the conclusion that with a larger sample size and/or more demanding conditions, a greater difference would be seen. Future studies should evaluate the use of graduated compression socks using more sophisticated, controlled techniques. Further research could also consider full-length of differing levels of pressure. There also remains a need for research examining the effectiveness of full-length to stimulate the proprioceptive system of balance in differing populations from the present study – including trained males, females, and older individuals.

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Appendix A: Subject Medical Questionnaire

Compression Sock Balance Study- Medical Questionnaire			
Name: _____			
Address:	City/State:	Zip:	
Telephone #:	Email Address:		
Birth Date:	Age:		
Weight:	Height:		
Race/Ethnic Background (Circle All That Apply):			
Hispanic	Black/African Americas	Asian	White/Caucasian
Islander	Native American	Other (specify): _____	
Do you engage in regular physical activity? (30 min/day for at least 5 days/week)		Yes	No
Have you ever engaged in organized gymnastics, tumbling, cheerleading, or dance?		Yes	No
If YES, please specify which: _____		For how long? _____	
Do you currently engage in organized gymnastics, tumbling, cheerleading, or dance?		Yes	No
If YES, please specify which: _____			
With which leg would you kick a soccer ball?		Right	Left
Have you had a previous ankle, knee, or hip injury in this leg?		Yes	No
If YES, please specify: _____		How long ago was the injury? _____	
Are you currently under treatment for the injury?		Yes	No
Do you have any vestibular disorders?		Yes	No
Do you suffer from vertigo?		Yes	No
Do you have any balance disorders?		Yes	No
Do you require corrective vision wear (glasses or contacts)?		Yes	No
Do you have an allergy to latex socks?		Yes	No

Appendix B: IRB Approval



INSTITUTIONAL REVIEW BOARD
119 College Drive #1147 | Hattiesburg, MS 39406-0001
Phone: 601.266.1997 | Fax: 601.266.4377 | www.usm.edu/instanta/institutionalreviewboard

NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16021601
PROJECT TITLE: Influence of Compression Socks on Unilateral Balance in Females
PROJECT TYPE: New Project
RESEARCHER(S): Alex Catson
COLLEGE/DIVISION: College of Health
DEPARTMENT: Kinesiology
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Expedited Review Approval
PERIOD OF APPROVAL: 04/05/2016 to 04/04/2017
Lawrence A. Hoisman, Ph.D.
Institutional Review Board

Appendix C: Long Form Consent



INSTITUTIONAL REVIEW BOARD LONG FORM CONSENT

LONG FORM CONSENT PROCEDURES

This completed document must be signed by each consenting research participant.

- The Project Information and Research Description sections of this form should be completed by the Principal Investigator before submitting this form for IRB approval.
- Signed copies of the long form consent should be provided to all participants.

Last Edited August 29th, 2014

Today's date:		
PROJECT INFORMATION		
Project Title: Influence of Compression Socks on Unilateral Balance in Females		
Principal Investigator: Alex Carlson	Phone: 601-325-6238	Email: alex.carlson@eagles.usm.edu
College: Health	Department: Kinesiology	
RESEARCH DESCRIPTION		
<p>1. Purpose:</p> <p style="margin-left: 20px;">(Describe purpose of the investigation, why it is being performed and what use may be made of the results.)</p> <p>The purpose of the investigation is to study the effect that a compression sock has on the unilateral balance of college-age female subjects. It is being performed in order to better understand the possible use of compression garments/socks to enhance unilateral balance. The results of this study may be used to initiate further studies in regard to compression garments/socks.</p>		
<p>2. Description of Study:</p> <p>If I choose to participate in this study, I understand that I will need to complete a general medical questionnaire in order to examine my eligibility for the study. I understand that only subjects without previous ankle, knee, or hip injuries will be considered (as their balance might already be altered). If eligible for the study, I will be asked to sign up for two 30-minute time slots to discuss what is to be expected of the researcher and myself throughout the study, to familiarize myself with the equipment, and to carry out the study. I understand that the testing will be done using a Biodex Balance System SD – a machine that measures and records both static and dynamic balance. Testing will involve the wearing of a compression sock with an 18-25 mmHg level of compression. I will be asked to refrain from any strenuous activity for at least 24 hours prior to testing. I understand that my unilateral balance on my dominant leg will be measured for eight separate measurements – one while wearing the compression sock on a static platform with eyes opened, one while not wearing the compression sock on a static platform with eyes opened, and the same two measurements will be done with eyes closed. Each of the previous four conditions will also be done on a moveable platform. For each condition, I will stand on the Balance System for three 30-second trials, then I will step off of the instrument. I will be barefoot for each measurement done without the compression socks. I understand that there will be some amount of time in between each measurement in order to allow my ankle joint to "rest" before taking further measurements. Following the testing period, a brief subjective analysis will be asked of me in order to determine my own perception of the effectiveness of the compression socks in enhancing proprioception (joint position awareness) and/or joint stability. In all, I will be expected to be present for testing for a total of 2 days – 1 to be briefed on the study and to carry out the four of the conditions and 2 to complete the remaining four conditions. Each testing day, I need to dedicate 30 minutes of my time to the study. I understand that I can withdraw from the study without reason at any point throughout testing.</p>		

[Describe the experimental procedure(s), including duration, amount of time required of the participants, number of participants, restrictions on normal activities, invasive techniques etc.]

3. Benefits:

The participants will receive no added incentives for their participation apart from the knowledge about their own unilateral balance.

[Describe any benefits that may occur to the participant or to others as a result of participation in the study, including all benefits or payments. If the potential for medical injury exists, identify treatment procedures or the absence thereof.]

4. Risks:

Risk associated with the investigation are minimal. However, guard rails are positioned on either side of the balance system in order to reduce risk of falling. In addition, the researcher will stand behind the balance system as each subject stands on it to insure safety. There is a potential risk of allergic reaction to the compression garment, but subjects answering that they have a known allergy to latex will not be considered for the study.

[Describe any known physical, psychological, social, or financial research-related risks, inconveniences, or side effects (expected and potential) and indicate what measures will be taken to minimize them if the potential for medical injury exists, identify treatment procedures or the absence thereof.]

5. Confidentiality:

The principal investigator will maintain participant confidentiality apart from herself and the co-principal investigator. Data will be stored on a password-protected computer to which only the investigator will have access, and subjects will be identified by pseudonyms. After no more than three years, all data collected for this investigation will be deleted. Results will be generalized as a whole.

[Describe confidentiality procedures. Detail the extent, if any, to which confidentiality of records identifying the participants will be protected.]

6. Alternative Procedures:

There are no alternative procedures.

[Describe alternatives to participation that will be presented to participation in the study (generally another accepted course of therapy or diagnostic procedure etc.)]

7. Participant's Assurance:

This project has been reviewed by the Institutional Review Board, which ensures that research projects involving human subjects follow federal regulations.

Any questions or concerns about rights as a research participant should be directed to the Chair of the IRB at 601-265-5987. Participation in this project is completely voluntary, and participants may withdraw from this study at any time without penalty, prejudice, or loss of benefits.

Any questions about the research should be directed to the Principal Investigator using the contact information provided in Project Information Section above.

CONSENT TO PARTICIPATE IN RESEARCH

Participant's Name _____

Consent is hereby given to participate in this research project. All procedures and/or investigations to be followed and their purpose, including any experimental procedures, were explained to me. Information was given about all benefits, risks, inconveniences, or discomforts that might be expected.

The opportunity to ask questions regarding the research and procedures was given. Participation in the project is completely voluntary, and participants may withdraw at any time without penalty, prejudice, or loss of benefits. All personal information is strictly confidential, and no names will be disclosed. Any new information that develops during the project will be provided if that information may affect the willingness to continue participation in the project.

Questions concerning the research, at any time during or after the project, should be directed to the Principal Investigator with the contact information provided above. This project and this consent form have been reviewed by the Institutional Review Board, which ensures that research projects involving human subjects follow federal regulations. Any questions or concerns about rights as a research participant should be directed to the Chair of the Institutional Review Board, The University of Southern Mississippi, 118 College Drive #5147, Hattiesburg, MS 39400-0001, (601) 296-5997.

Include the following information only if applicable. Otherwise delete this entire paragraph before submitting for IRB approval: The University of Southern Mississippi has no mechanism to provide compensation for participants who may incur injuries as a result of participation in research projects. However, efforts will be made to make available the facilities and professional skills at the University. Participants may incur charges as a result of treatment related to research injuries. Information regarding treatment or the absence of treatment has been given above.

Research Participant

Person Explaining the Study

Date

Date