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COMPARISON EFFECTS OF TAPE AND THE MCDAVID ULTRA BRACE IN
LIMITING THE AMOUNT AND RATE OF ANKLE INVERSION

by

Leah M. Pataki, M.A.

A Thesis
Submitted to the
Faculty of The Graduate College
in partial fulfillment of the
requirements for the
Degree of Master of Arts
Department of Health, Physical Education, and Recreation

Western Michigan University
Kalamazoo, Michigan
December 2004

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Leah M. Pataki, M.A.

COMPARISON EFFECTS OF TAPE AND THE MCDAVID ULTRA BRACE IN LIMITING THE AMOUNT AND RATE OF ANKLE INVERSION

Leah M. Pataki, M.A.

Western Michigan University, 2004

The ankle joint is among one of the most common sites for injury, accounting for 86% of all injuries. Commonly, athletic tape or an ankle brace is used to prevent or protect ankle injuries from occurring and/or re-occurring. The purpose of the study was to compare the effectiveness of athletic tape and the McDavid Ultra brace in limiting the amount and rate of ankle inversion when using dynamic ankle inversion. Subjects (6=Males, 12=Females) completed ten trials on an inversion platform under the following conditions: no-tape (control) and two bracing conditions (athletic tape and McDavid Ultra Brace). A 2 x 3 repeated measures ANOVA showed that there was a significant difference in the amount of ankle inversion¹. The McDavid brace significantly reduced the rate inversion (394.49 deg/s) when compared to the tape (524.19 deg/s) and the control (687.89 deg/s). In addition, the tape condition significantly reduced the rate of ankle inversion when compared to the control. The McDavid brace was significantly better than ankle taping in reducing the amount and rate of ankle inversion, which is useful for a clinician when trying to rehabilitate an injury or trying to protect the ankle from further injury.

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INTRODUCTION

The ankle joint is among one of the most common sites for injury in an individual who participates in athletic activities. Of the injuries that can occur at the ankle joint, 86% are ankle sprains.¹⁻²⁰ Most sprains affect the lateral complex and structures of the ankle and foot when an individual is landing, the foot is plantar flexed and internally rotated. Along with the lateral structures, the peroneal muscle group is suggested to be the “last line of defense,” by dynamically stabilizing the lateral complex from that motion.¹⁻²⁰ Inversion sprains may cause muscular damage of the peroneus longus and peroneus brevis muscles. Peroneus longus neuromuscular function is critical in supporting and reacting at the ankle-foot complex, against an inversion mechanism injury. According to Johnsons¹³, peroneal muscle weakness can be considered one of the four main causes of recurrent lateral ankle sprains; along with mechanical instability tibiofibular sprain and proprioceptive weakness⁵. Because of this peroneus longus reaction time/latency, during a “simulated” ankle sprain has been predominantly the focus of stable and unstable ankles.

Due to the frequency of ankle injuries, a considerable amount of research has been conducted to examine how to prevent and protect such injuries. Ankle bracing and taping reduce ankle injury and injury frequency rates due to the mechanical support offered by such devices.

The most commonly known form of applied external ankle devices is tape. Numerous studies have been conducted on the properties and function of tape. The most basic function of athletic tape, when applied to the ankle, is to react as an extra “external ligament”.¹⁻²⁰ The theory/idea behind the extra reinforcement is to restrict extreme and injury causing motions that could take place at the ankle joint. The results of these studies and others are controversial and widely debated. Some studies report that tape loses up to 40% of its restrictive properties after ten-minutes of exercise.^{9,12,13} Results from these studies affected how individuals in the sports medicine field tried to protect individuals who had sustained ankle injuries. If tape loses its properties, then the desired restrictions never occur, leaving the injured ankle unprotected from possible further injury. However, more recent studies have found that tape does retain its restrictive properties following exercise and as a result still provides protection from injury.^{1,2,8,14} Meaning, athletic tape is still the most common and effective form of external bracing used by sports medicine personnel.

Other concerns about tape have focused on motor performance and cost effectiveness. Based upon the many discrepancies and controversial results found with tape, external prophylactics become more widely used due to the more restrictive properties. In terms of cost effectiveness, external bracing is a one-time cost that tends to pay for itself with the application of multiple uses. Athletic tape is a one-time application and is not very cost effective. Numerous studies have been conducted the past forty years on external brace application comparative to athletic tape.^{1-3,5-7,9,11-19} Some of the more commonly known braces tested were: the Air Cast

(Aircast, Inc., Summit, New Jersey), the Swed- O lace up (Swed-O –Universal, Inc., North Branch, Minnesota), Ankle Ligament Protector (DonJoy Orthopedic, Carlsbad, CA), the McDavid lace-up (McDavid Sports Medical Products, Woodbridge, Il), and the Active Ankle (Active Ankle Systems, Inc. Louisville, KY). Most of these studies have compared the effectiveness of taping and bracing on joint mechanics by evaluating passive ROM, isokinetic dynamometer strength, or dynamic ROM.^{1-3,5-7,9,11-19} Most of the studies included the use of trapdoors and or inversion platforms, to specifically look at the amount and rate of motion that takes place at the ankle joint. According to Cordova and et al,¹ the following conclusions were considered a consensus regarding the effects of external brace support on the ankle-foot ROM. Before exercise, semirigid braces restricted inversion ROM 21.3% more than tape and 26.2% more than lace-up braces. After exercise, semirigid braces restricted inversion ROM 72.1% more than tape and 59.5% more than lace-up braces. No significant differences existed in inversion ROM restricted between the tape and lace-up brace conditions before (15.9% and 14.9%, respectively) or after exercise (7.3 degrees and 10.6 degrees respectively). Concluding, semirigid external applications to the ankle would provide better protection and more reinforcement to structures that are injured.

The McDavid Ultra ankle brace is considered a semi-rigid ankle brace. Unlike its counterparts, this brace is constructed so that it is one continuous piece of plastic that supports and encloses around the ankle and is secured with one piece of Velcro. It is one of the newest braces out on the market, and has yet to be tested.

The purpose of our study is to investigate the restrictive properties of the McDavid Ultra brace comparative to athletic tape and no tape in limiting the amount and rate of ankle inversion, and peroneus longus, peroneus brevis, and tibialis anterior muscle latency.

METHODS

Subjects

Eighteen subjects (6 males / 12 females; 22.4 ± 1.98 years; 74.28 ± 12.69 kg; $1.72 \pm .08$ m) volunteered for our study.

Subjects were selected to participate in our study if they met the following criteria: (1) were acknowledged as students, faculty, or staff, (2) at least eighteen of age, (3) no previous history of ankle or lower leg injury within the past four weeks, (4) no history of ankle or lower leg surgery within the past year, (5) pain free gait, (6) not currently involved in other research projects, (7) display full range of motion and strength at the ankle, and (8) no history of bone or joint disease (8) were able to fit into shoes provided for study. To assure the recruited subjects met our study inclusion criteria all potential subjects were required to complete a Par-Q and inclusion/exclusion questionnaire prior to the start of the study. All subjects read and signed an informed consent document that was approved by the Human Subjects Institutional Review Board.

Instruments and Procedures

An inversion platform with a foot support base that rotates 35 degrees after depressing an electronic switch was used to induce dynamic ankle inversion (Figure 1). The inversion platform was instrumented with an electronic goniometer so that

the angle of the platform could be obtained. An electronic goniometer was also placed on the heel of the subject's shoe and lower leg to record ankle inversion/eversion motion.

Surface electromyography (EMG) was used to record the muscle latency of the peroneous longus, peroneous brevis, and tibialis anterior musculature. A ground electrode was placed on the tibial tubercle. The electrode sites were prepared by removing the hair in the area, lightly roughing the skin with gauze and cleansing the area with rubbing alcohol to lower the amount of impedance below 3000Ω . The electrodes were self-adhesive but were re-enforced with power-flex athletic wrap to prevent misplacement during testing. The placement of the electrodes was marked to ensure accurate replacement of the electrodes if they became dislodged during testing. The EMG signals were recorded with Noraxon Dual Electrode, (*Scottsdale, Arizona*) placed over the muscle belly parallel to the muscle fibers. The Noraxon electrodes have a fixed inter-electrode distance of 2 cm, with a 1 cm circular recording area. All electrode placements were verified by manual muscle testing. We marked the positions of the electrodes to prevent misplacement if they became dislodged or fell off during the exercise bout for accurate placement on the other testing days.

EMG and goniometer signals were sampled at 1000 Hz using a Dell computer interfaced to a Noraxon Myosystem (Scottsdale, AZ) EMG amplifier by a Keithley-Metrabyte (Taunton, MA) DPCA-3107, 16-bit analog-to-digital converter. The EMG signals were differentially amplified with a gain of 1000 and a bandwidth of 16-1000Hz at -3dB using a Noraxon EMG system. The Noraxon amplifiers have an

input noise below 1 mV RMS and an effective common mode rejection ratio of 135dB.

Experimental Conditions

Testing was conducted before and after exercise under three conditions: no tape (control), athletic tape with pre-wrap and McDavid Ultra Ankle brace. The order of testing was counterbalanced using a balanced Latin square. The testing of each condition occurred on separate days within a 3-week time frame, with sessions lasting no more than 45 minutes. All subjects' wore Asics Gel shoes for all three experimental conditions.

Taping Method

The primary investigator applied a closed basketweave ankle tape application to all subjects. The tape application included 3.8 cm (1.5 in) zinc oxide tape (Johnson & Johnson), foam pre-wrap (Muller Sports Medicine, Inc, Prairie du Sac, WI), heel and lace antifriction pads (Cramer Products, Inc., Gardner, KS) containing a small amount of lubricant (Cramer Products Inc.) and tape adherent spray (Cramer Products, Inc.).

Brace

The primary investigator applied each brace condition to all subjects. The size of the brace applied to the subject was based from the recommendation of McDavid Company, which used shoe size as the determining factor. For proper fitting, the insole of the shoe was removed and the Ultra Ankle heel cup is placed at

the bottom of the shoe, the insole is then replaced over the brace heel cup in the shoe . The subject was then instructed to place his or her foot in the shoe, then slide the bottom of the brace toward the back of the shoe, as far as it would go. The subject then secured the strap and laced up the shoe.

Inversion Platform Training

Prior to testing the subjects were trained on the inversion platform. Subjects practiced dynamic inversion by gradually increasing the amount of body weight placed on the right leg. Experimental testing began, when the subject was able to undergo dynamic inversion with full weight placed on the right foot, using only the left great toe for balance.

Exercise Bout

Once pre-testing on the inversion platform was completed, the subject had the electrical leads disconnected from the EMG machine and their foot released from the restraints on the inversion platform. The subjects then completed an exercise bout consisting of: a 10-minute treadmill run at 4.2 –5.2 mph, three sets of ten repetitions of touch jumps, and two sets of five repetitions of lateral shuffles.

Testing

Data were collected for each subject on three separate days. The subjects wore their own socks and the same low-top Asics Gel athletic shoe (Asics Corp.USA) for each of the testing conditions.

Once the athletic tape, the ankle brace, or nothing was applied, subjects were pretested, exercised, and then were post tested.² To minimize the effects of movement of the foot within the athletic shoe during inversion testing, subjects were instructed to tightly tie his/her shoe before each set of inversion platform tests. Also, the subject was instructed that during the exercise bout to tighten the ankle brace, should it feel loose and to tighten it before the last set of post tests.

Prior to inversion platform testing, a goniometer was attached to the back of the heel of the subject's shoe and to the base of the gastrocnemius in line with the Achilles tendon. Once the goniometer was placed onto the shoe, it was secured at the heel with wing-nuts and at the top of the calf with Power-Flex tape (Andover Coated Products, Salisbury, MA). The subject then stood on the inversion platform, placing his or her weight on the right leg and using only the great toe of the left leg for balance.

Subjects stood on the inversion platform facing away from the investigator to avoid anticipation of the platform drop. They were instructed to stand with most of their weight on their dominant foot, using the other foot for balance (Figure 1). The ankle goniometer was zeroed with the subject in this balanced position. The subject was instructed to relax the ankle and "roll" into the drop of inversion. At random intervals the platform was dropped. Each trial was visually inspected and saved for analysis, as long as there was no evidence showing muscle preactivation or a delay between the drop of the platform and the inversion movement of the foot. Ten trials

of dynamic ankle inversion were collected for all three conditions. Most subjects required 10 to 15 trials to complete 10 acceptable trails.²

Once the subject had undergone pre-testing, the ankle goniometer was removed and the subject completed the exercise bout. After completing the exercise bout, the goniometer was reattached and the subject was post-tested on the inversion platform.

Statistical Analysis

Specially written Visual Basic software was used to compute the amount of ankle inversion, maximum rate of ankle inversion and the muscle latency for the peroneus longus, peroneus brevis and tibialis anterior muscles. The amount of ankle inversion was defined as the difference between the ankle position at the onset of platform drop and the point of maximum ankle inversion. The rate of ankle inversion was computed using the first central difference formula and the maximum rate attained between the onset of platform drop and the point of maximum inversion was defined as the maximum rate of ankle inversion.

Baseline EMG activity for each trial was defined as the mean magnitude of the EMG activity for 100 ms preceding the drop of the inversion platform. Onset latency for the muscles tested was defined as the time from the start of the platform drop to the time when the magnitude of the EMG signal reached or exceeded a level of 10 standard deviation above the baseline activity. A 2 x 3 repeated measures ANOVA was used to test the effects of exercise (pre, post) and bracing conditions (control, tape, McDavid) on the ten trial averages of the following dependent

variables: amount of inversion, the maximum rate of inversion, and muscle latency of peroneus longus, peroneus brevis, and tibialis anterior. Alpha was set at 0.05 for all comparisons.

RESULTS

The mean and standard deviation for the dependent variables are presented in Table 1. There was a significant exercise by condition interaction [$F(2,30) = 4.12$, $p = .03$, power = .68] for the amount of ankle inversion. Post hoc tests revealed no significant exercise effects for the amount of ankle inversion. Prior to the exercise bout, the amount of ankle inversion for the McDavid brace 16.11° was significantly different from the tape 23.50° and the no-tape 39.8° conditions. The tape condition was also significantly different from the no-tape condition prior to exercise. After exercise, the McDavid brace 19.43° was significantly different from the tape 27.55° and no-tape 36.91° conditions. The tape 27.55° was also significantly different from no-tape 36.91° after exercise.

The maximum rate of inversion was significantly different between the taping and bracing conditions [$F(2,30) = 40.84$, $p = .001$, power = 1.00]. The McDavid brace significantly reduced the rate inversion 394.49 deg/s when compared to the tape 524.19 deg/s and the no-tape 687.89 deg/s. In addition the tape condition significantly reduced the rate of ankle inversion when compared to the control, no-tape condition.

There were no significant differences between the ankle taping/bracing conditions in the time to maximum inversion. As shown in Table 1, the time to maximum inversion ranged from 28.0 ms to 36.9 ms.

There was a significant exercise effect for peroneus longus muscle latency [$F(1,15) = 7.15, p=.02, \text{power} = .71$]. The peroneus longus muscle latency prior to exercise of 56.6 ms was significantly longer than after the exercise bout, 52.9 ms. In addition, there was a significant difference in peroneus longus muscle latency between the taping/bracing conditions [$F(2,30) = 13.10, p = .001, \text{power} = .99$]. The no-tape condition was significantly shorter, 49.05 ms than both the tape 55.38 ms and brace 59.89 ms conditions. There was no difference in the peroneus longus muscle latency between the tape and brace conditions.

There was a significant exercise by bracing interaction [$F(2,30) = 3.33, p = .04, \text{power} = .585$] for peroneus brevis muscle latency. Prior to exercise the tape peroneus brevis latency 56.27 ms was significantly different from the brace 63.55 ms condition. After exercise, no-tape muscle latency was significantly different 55.43 ms from the brace condition 65.24 ms. Following exercise, the tape condition peroneus brevis muscle latency 55.53 ms was significantly different from the brace condition muscle latency of 65.24 ms.

There were no significant differences in the muscle latency for the tibialis anterior muscle latency between the taping/bracing conditions.

DISCUSSION

The McDavid Ultra brace was significantly more effective than ankle taping in reducing the rate and amount of ankle inversion. While both the McDavid Ultra brace and ankle taping reduced ankle inversion and the rate of ankle inversion, when compared to control, the McDavid Ultra brace may be the best functional choice for the injured athlete since it does not inhibit plantar and dorsi flexion. In addition, the ankle brace has the added advantage of being reusable and can easily be used by the athlete.

Earlier studies on the efficacy of ankle taping upon restricting the amount and rate of ankle inversion suggested that athletic tape lost anywhere between 15-40% of its effectiveness after exercise, showing that athletic tape was an ineffective tool in helping to prevent injuries.^{3-5,12} The exercise sessions during these studies were either sport specific, functional, or used ankle passive ROM exercises. It has been shown that there is an “exercise effect,” thus increasing ankle joint movement, due to soft tissue response to exercise. Some researchers have suggested that the exercise effect is really a “warming-up” effect of the muscles that support the ankle mortise.⁹ The increase in temperature and blood flow that occurs to the structures of the ankle tend to increase the range of motion and plausibility of the structures. The increase in temperature can also transfer from the body to the applied external ankle device, causing changes in the function of the device. Other researchers have observed that

the loosening of the tape could be attributed to a separation or tearing of tape fibers caused by the mechanical stresses put on the tape or by moisture from the skin found post exercise.^{9,11} Additional moisture found in tape will cause tape to lose its adhesive properties, therefore, decreasing its attachment to the ankle. If tape is not properly adhered to the ankle, the amount of restraint that is provided is decreased. Other studies, have shown that even though there is a slight increase in the range of motion that occurs at the ankle joint, tape does not lose that much of its restrictive properties making it ineffective in protecting the ankle during exercise or activity. We did not find a significant exercise effect for the amount or rate of ankle inversion, suggesting that both ankle taping and the McDavid ankle brace retain their restrictive properties following exercise.

In previous studies involving external bracing, comparisons were made to different type of braces and tape, and their effects and properties in limiting inversion-eversion at the ankle joint. Cordova and et al¹, found was that semi-rigid bracing provided greater eversion ROM restraint compared with tape and lace-up brace conditions before (19.8° semirigid, 9.5° tape, 14.4° lace-up) and after exercise (24.9° semirigid, 7.1° tape, 8.9° lace-up).

However, there have been some differences found between different types of bracing.^{1,20} The more semi-rigid braces restrict more movements at the ankle joint that involve inversion and eversion, in comparison to tape and no-tape. Such braces would include the Air Cast, Active Ankle, and DonJoy Anterior Ligament Protector. The lace-up or cloth type braces (Swed-O, McDavid lace up, and cloth wraps) have

shown to restrict movements that occur during inversion, eversion, and plantarflexion; however, it needs to be noted that both the Swed-O and McDavid lace-up braces have the capability to be more rigid by adding plastic inserts to both medial and lateral aspects to the brace, but have not been tested. The most effective way to replicate the movements needed to test motions of the ankle is to use either an inversion platform or trapdoor. These types of instruments are able to replicate the motions of an ankle sprain, but are in a controlled setting where the investigator controls which movements are preformed and to what degree they are performed at. The use of goniometers that are attached to the devices and to the rear of the heel cup or to the back of the subject's calf allows the amount and rate of the motions to be calculated and observed.

An important result to note was the significant difference seen in the amount of ankle inversion that was restricted by the McDavid Ultra ankle brace. There was approximately a 10° difference between the brace and the athletic tape. The other result to notice was the less than 3° increase that was seen post exercise, showing that the brace had not lost a great deal of its restrictive properties. The results show that the McDavid Ultra ankle brace provide a better "external ligament" protectiveness than tape does before and after exercise. The fact that the brace still provided support after exercise, shows that the brace can withstand conditions that affect tape, making the McDavid Ultra brace the most effective of the two external devices. The restrictive, materialistic, and design properties make the McDavid Ultra brace

versatile in its applications not only for injured ankles, but can provide an environment to prevent injuries.

Peroneus longus neuromuscular function is critical in dynamically supporting the ankle-foot complex against an inversion mechanism of injury. As a result, peroneal reaction time, or latency, during a simulated ankle sprain has been predominately studied in normal and chronically unstable ankles.^{1,12} Due to the complexity and safety of subjects, the use of inversion trapdoors and platforms to simulate an ankle injury has been widely accepted in trying to simulate a dynamic state of an “ankle sprain”.¹ In our study, we used the inversion platform, controlling the platform to a 35° drop providing enough stress to activate the peroneal muscles and keeping a controlled environment. Konradsen and Raven¹⁶ found that in a stable ankle peroneal reaction time was 72 ms where an unstable ankle averaged 85 ms, correlating that instability is associated with an increase in peroneal reaction time. In our study, peroneus longus reaction time was no more than 60.0 ms (McDavid brace) and in the study conducted by Demming and et al³, peroneal reaction times were looked at and between 10 different bracing conditions (semi-rigid and soft braces). Their results showed that there were no significant differences between the braces, however the average reaction time was 51.2 ms \pm 0.9 ms. Maximum inversion angles were 39° \pm 6° for the control group and the braces recorded to significantly restrict motion to 20-33°. In our study, there was an exercise effect that was seen between the conditions. As the structure of the ankle became “warmed up” from the exercise by increasing temperature and blood flow, the amount of range of motion increased

during the post-test. The McDavid brace restricted approximately 10° more than tape and approximately 20° more than no-tape.

We also examined tibialis anterior muscle latency. We found that there was a significant exercise effect for the peroneus longus muscle. Prior to exercise peroneus longus reaction time was 56.6ms and 52.9 ms after exercise. However, like in Demming et al³, no significant difference was found between the two different bracing conditions and peroneus longus. However, we did find that there was a significant exercise effect in the bracing conditions and peroneus brevis muscle latency. The longest time was that of the brace at 63.5 ms prior to exercise, however, the no-tape condition recorded at 61.5 ms prior to exercise. After exercise, the only condition that significantly changed was the McDavid brace condition, peroneus brevis latency actually increased to 65.2 ms.

CONCLUSION

McDavid Ultra ankle brace and tape significantly reduced the amount and rate of ankle inversion. The McDavid brace was significantly better than ankle taping in reducing the amount and rate of ankle inversion. In comparison and application, the McDavid Ultra ankle would be the external ankle device of choice, when trying to provide extra external protection and rigidity to an injured ankle.

Table 1. Experiment Variables by External Ankle Devices and Exercise Conditions (Mean ± SD)

	No Tape	Tape/Prewrap	McDavid Ultra Brace
Total Inversion (°)			
Before Exercise	39.8 ¹ ± 10.8	23.5 ² ± 5.3	16.1 ± 4.8
After Exercise	36.9 ¹ ± 9.7	27.5 ² ± 8.1	19.4 ± 5.1
Difference	2.9 ± 1.1	4.0 ± 2.8	3.3 ± 0.3
Time to Maximum Inversion (ms)			
Before Exercise	36.9 ± 9.8	31.9 ± 18.9	28.0 ± 9.5
After Exercise	34.1 ± 9.9	30.5 ± 11.4	32.9 ± 11.0
Difference	2.8 ± 0.1	0.4 ± 7.5	4.9 ± 1.5
Maximum Inversion Velocity (°/s)			
Before Exercise	679.0 ¹ ± 150.0	507.1 ² ± 145.4	364.3 ± 89.4
After Exercise	696.8 ¹ ± 177.6	541.2 ² ± 160.5	424.7 ± 95.1
Difference	17.8 ± 27.6	34.1 ± 15.1	60.4 ± 5.7
Peroneus Longus Latency			
Before Exercise	51.2 ¹ ± 10.8	57.3 ± 11.0	60.0 ± 9.6
After Exercise	45.6 ¹ ± 8.9	53.5 ± 9.1	59.7 ± 7.4
Difference	5.6 ± 1.9	3.8 ± 1.9	0.3 ± 2.2
Peroneus Brevis Latency			
Before Exercise	61.5 ³ ± 9.4	56.3 ² ± 10.4	63.5 ± 8.0
After Exercise	55.4 ± 11.5	55.5 ² ± 7.9	65.2 ± 8.2
Difference	6.1 ± 2.1	0.8 ± 2.5	1.7 ± 0.2
Tibialis Anterior Latency			
Before Exercise	53.1 ± 9.3	55.3 ± 9.7	61.6 ± 10.2
After Exercise	48.5 ± 9.2	55.9 ± 9.1	62.5 ± 8.8
Difference	4.6 ± 0.1	0.6 ± 0.6	0.9 ± 1.4

¹No tape significantly different from tape and brace

²Tape significantly different from brace

³No Tape significantly different from brace

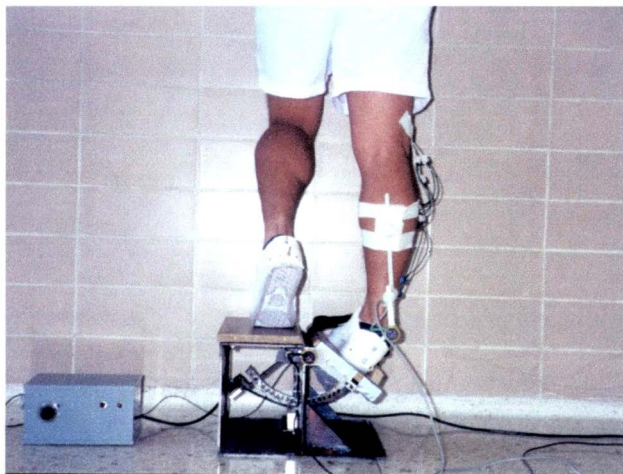
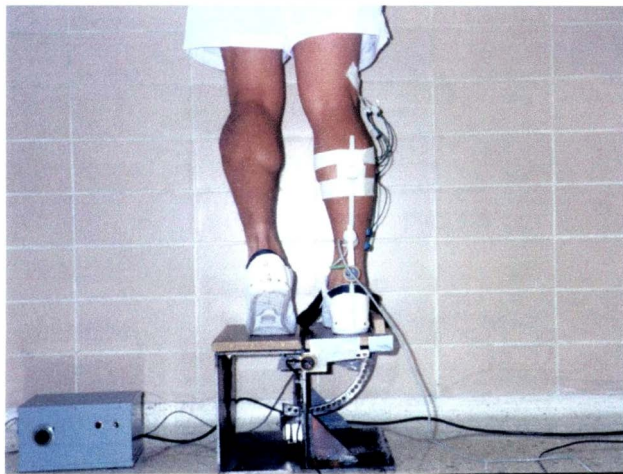


Figure 1. Inversion Platform Start/Platform Down

APPENDICES

APPENDIX A
HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD LETTER OF APPROVAL



Date: October 9, 2003

To: Mark Ricard, Principal Investigator
Leah M. Pataki, Student Investigator for Thesis

From: Mary Lagerwey, Ph.D., Chair

A handwritten signature in cursive script that reads "Mary Lagerwey".

Re: HSIRB Project Number: 03-09-03

This letter will serve as confirmation that your research project entitled "The Comparison of the Effect of Tape and the McDavid Ultra Ankle Brace on Limiting the Amount and Rate of Ankle Inversion During an Inversion Stress Testing" has been **approved** under the **full** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: September 17, 2004

**APPENDIX B
INCLUSION/EXCLUSION QUESTIONNAIRE**

Inclusion/Exclusion Questionnaire

Please read the questions carefully and answer each one honestly. Circle YES or NO.

1. Are you between the ages of 18-45?	YES	NO
2. Have you had any injury to your ankle in the past 4 weeks?	YES	NO
3. Are you currently involved in another study involving the lower extremity?	YES	NO
4. Have you undergone any surgical procedure involving the lower extremity within the past year?	YES	NO
5. Do you have full range of motion in both of your ankles?	YES	NO
6. Do you fit in the shoe size range: Women's 6-10 Men's 9-13	YES	NO
7. Do you currently have pain when you walk?	YES	NO
8. Do you have a history of joint or bone disorders? (i.e. arthritis, fibromyalgia, chronic tendonitis, etc.)	YES	NO
9. Are you allergic to rubbing alcohol?	YES	NO

I have read, understand, and completed this questionnaire. Any questions I had were answered to my full satisfaction. I am aware that if I do not meet the inclusion criteria for this study I will not be permitted to participate. However, I understand I will receive no penalty, risk of loss of service I would otherwise receive or negative affects on me or my status in HPER classes if I do not meet the inclusion criteria.

Name: _____

Date: _____

Signature: _____

Witness: _____

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