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The effects of a functional derotational knee brace on the single-leg hop, timed-hop, and stability of NCAA Division II athletes

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The effects of a functional derotational knee brace on the single-leg hop, timed-hop, and stability of NCAA Division II athletes

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Chapter One

Introduction to the Study

The incidence of anterior cruciate ligament (ACL) injuries has tripled in the past two decades (Aune, Cawley, & Ekeland, 1997). An ACL injury typically occurs when the athlete has their foot planted, and there is external tibial rotation at the knee. The ACL helps to limit rotation and instability at the joint. Instability leads to damage to a partially torn ACL, newly reconstructed ACL, or the meniscus (Caubaud & Rodkey, 1985; Cook, Tibone, & Redfern, 1989; Larson, 1990; Moore, 1992). After the primary injury to the ACL, a functional derotational brace is usually prescribed by the athletes' physician (Shelton, Barrett, & Dukes, 1997; Wojtys, Kothari, & Huston, 1997). Derotational braces are designed to provide stability to the knee joint by limiting the amount of rotation that occurs (Beynnon, Johnson, Fleming, Peura, Renstrom, Nichols, & Pope, 1997; Branch & Hunter, 1990; Cook et al., 1989; Noyes, 1984; Wirth & Delee, 1990; Wichmann & Martin, 1998).

Many studies have been performed on custom-fit knee braces (Beynnon et al., 1997; Browenstein, 1998; Risberg, Holm, Steen, Eriksson, & Ekeland, 1999). However, not all athletes are returned to play wearing a custom knee brace. More commonly, athletes are given off-the-shelf knee braces.

Previously, there were no significant side effects of wearing the brace, such as increase injury rates, but there are still questions raised about how detrimental these functional knee braces are to the athletes' performance capabilities (Caubaud & Rodkey 1985; Cawley, France & Paulos, 1991)

There is a need for more extensive research with limited variables to show the effect of functional knee bracing on force production and stability. This will offer the athletes' more insight as to whether they want to compromise balance and force production while wearing the knee brace.

Purpose Statement

The purpose of this study was to measure the effects of functional knee bracing on power and dynamic stability in healthy athletes.

Operational Definitions

Closed-Kinetic chain exercises- Type of rehabilitation exercise in which the foot maintains constant contact with the floor or other stable platform.

Custom-fit knee brace - A knee brace that is molded from an athlete's leg to be fit and worn only by that athlete.

Functional Knee Brace- supports the knee when an athlete is returned to competition following an injury. Helps to let the athlete resume functional sports activity without future damage to internal structures.

Functional Tests- Agility tests that the athlete must perform before they are able to return to competition.

Mechanoreceptors- A nerve ending that is sensitive to mechanical pressures, such as muscle contractions.

Off-the Shelf knee brace - A design of knee brace that is not personally fit to the athlete's individual leg, but molded from certain girth parameters. This brace usually comes in sizes to fit the majority of the population.

Proprioception- The body's awareness to know it's position in space.

Stability- The ability to maintain a certain position with outside forces opposing the position.

Basic Assumptions

1. All of the subjects had the same motivation to participate in the study.
2. All of the participants were honest on their past medical history form.
3. The testing procedures were performed under the same conditions for each participant.

Limitations

1. The subjects were all uninjured, healthy individuals.
2. Participants were all between the ages of 18 and 24 years old.
3. The tests were not performed on a game surface.
4. There was a high subject drop-out rate.

Null Hypotheses

1. An athlete's single leg hop test will not be affected by wearing a functional knee brace
2. An athlete's timed hop test will not be affected by wearing a functional knee brace
3. An athlete's Biodex stability index will not be affected by wearing a functional knee brace

Chapter Two

Introduction

The knee is comprised of four primary ligaments, which are the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), and the lateral collateral ligament (LCL). These ligaments are commonly damaged during athletic activities, and knee braces are often used to return athletes to competition. Functional knee braces have been used in athletics since the late 1960's (Branch & Hunter, 1990). They have progressed and changed significantly from that time, but they essentially have the same features to protect athletes and allow them to return to competition. It is necessary to explain the anatomy of the knee, pathophysiology of ACL injuries, surgical reconstructions, and rehabilitation of the ACL deficient knee to understand knee function. Furthermore, functional testing, balance, and brace characteristics will be explained to provide a better understanding of knee brace function.

Anatomy of the ACL

The ACL and PCL are the primary stabilizers in the knee (Caubaud & Rodkey, 1985; Larson, 1985; Moore, 1992). The ACL is an intra-articular structure that consists of longitudinal fascicles that insert into the lateral femoral condyle and onto the tibial plateau (Moore, 1992). The average ACL varies in length from 31-38 mm long. The ligament consists of two separate bands that function to offer stability in both flexion and extension. The anteromedial bundle is taut in flexion while the posterolateral bundle is tight in extension (Caubaud & Rodkey, 1985; Muller, 1996).

The ACL lacks free nerve endings, which is why many athletes do not complain of pain with a complete tear. The blood that diffuses to the joint and stimulates free nerve endings causes the pain associated with an ACL tear. The serasanguinous fluid is indicative of damage to other structures within the knee, such as the ACL, PCL, MCL, joint capsule, and femoral condyles. The ACL has a poor blood supply, which hinders the healing process and prevents regeneration of the ligament. The ACL is unable to repair itself, which is why it must be reconstructed (Caubaud & Rodkey, 1985).

The ACL adds stability to the knee when coupled with the other three ligaments in the knee. The other ligaments are the LCL, MCL, and PCL. The muscles that cross the knee joint help to improve stability. These include the quadriceps group, gastrocnemious, and hamstrings group (Caubaud & Rodkey, 1985; Muller, 1996; Wojtys, et al., 1996).

Functions of the ACL

The ACL performs two major functions. The first function is guiding and stabilizing the femur and the tibia during flexion and extension. Excessive anterior translation on the femur causes damage to other structures in the knee (Caubaud & Rodkey, 1985). The second function of the ACL involves its viscoelastic properties. The viscoelasticity of the ligament allows it to adjust to separate motions at the same time, such as flexion and rotation. The elastic component also helps to decrease the torque of movements to an acceptable rate for the surrounding musculature. This usually occurs during the deceleration phase of motion, when added stress is placed on the knee ligaments and surrounding musculature (Larson, 1985; Moore, 1992).

Pathophysiology

There are two separate mechanisms in which the ACL becomes injured. Contact injuries to the ACL involve a forced external rotation with valgus loads applied from external mechanisms. However, with the increasing number of athletes, there is a steady incline of a non-contact hyperextension mechanism. There is often associated damage to the MCL and medial meniscus with a complete ACL tear (Caubaud & Rodkey, 1985; Cook et al., 1989; Daniel, Tone, Dobson, Fithian, 1994; Larson, 1985; Moore 1992; Nemeth, Lamontagne, Tho, Eriksson, 1997; Wojtys et al., 1996). Other mechanisms may include contact hyperextension, contact blows with the knee flexed, and non-contact ski injuries (Aune, et al., 1997; Caubaud & Rodkey, 1985; Daniel et al., 1994; Nemeth et al., 1997; & Wojtys et al., 1996).

Reconstruction and Rehabilitation of the ACL

As discussed before, the ACL does not regenerate itself due to the poor blood supply to the ligament. Therefore, when the ACL is torn, an athlete must consult with an orthopedic surgeon to decide if they want to operate to reconstruct the ACL (non-conservative) or rehabilitate (conservative) and not perform the surgery. Surgery is recommended for younger athletes who have a competitive future planned. Rehabilitation before and after the surgery is very difficult, and the athlete must be aware of the financial and time constraints placed on them by deciding to have the surgical procedure (France, Cawley, & Paulos, 1990).

The most commonly used methods of surgical reconstruction are a bone-patellar tendon-bone graft or hamstring tendon graft (Larson, 1990). Surgery is not recommended for older patients or for patients who want to decrease developing osteoarthritis (Caubaud & Rodkey, 1985). The patient must understand the significance of rehabilitation following the surgery and the importance of proper techniques. Failure to follow rehabilitation protocols would result in an almost certain failure of the surgery (Caubaud & Rodkey, 1985; Larson, 1990).

The alternative to surgery is conservative rehabilitation and possibly returning to play with a functional knee brace. However, without the ACL acting as the primary restraint to tibial translation and rotation, some believe that the athlete is at a competitive disadvantage (Larson, 1990). Closed kinetic chain exercises are stressed during the rehabilitative phase due to the decrease in shearing force. These exercises are performed while the foot has constant contact with the floor. This contact helps to induce muscular contractions that add to the stability of the knee (Bynum, Barrack, & Herbert, 1995).

Proprioception and Postural Stability

Proprioception is defined as the awareness of joint position in space as sensed by the Central Nervous System (CNS) (Swash, 1986). Mechanoreceptors provide the primary information to the CNS for limb position. These are found throughout the ACL, therefore disruption to the ACL often leads to a decrease in proprioception. This decrease leads to a decline in muscle function, which then is followed by instability of the joint (Beynnon, Ryder, Konradsen, Johnson, Johnson, & Renstrom, 1999; Swash, 1986).

Postural stability is the ability to maintain the center of body mass over the base of support. The ability of a person to maintain this stability is a combination of visual, vestibular, and proprioceptive neural input to the CNS (Schmitz & Arnold 1998). With a disruption of the ACL, an assumption is made that postural stability will be affected.

Functional Testing

The single-leg hop and timed-hop tests are two ways of testing a person's functional level following injury. Functional testing is widely used in the sports medicine arena because it is fast, easy to perform, and it requires minimal personnel to complete the testing process (Bolga & Keskula, 1997). These tests are designed to simulate the stresses placed on the knee and surrounding structures during athletic activities (Bolga & Keskula, 1997; Lephart, Perrin, Fu, & Minger, 1991).

Hop tests, by virtue of their high demands on motor control, are effective in examining motor skill and joint stability (Juris, Phillips, Dalpe, Edwards, Gotlin & Kane, 1997). Testing measures that examine how far or how high a jump is performed measure force production (Juris et al., 1997). The single-leg hop test measures force as how far a maximal jump can be performed. The timed-hop examines how quickly that force can be produced. Previous studies have shown that hop tests can identify poor motion control or poor motor function which can potentially predispose an individual to future injury (Bolga and Keskula, 1997; Juris et al., 1997).

Knee Bracing

Knee bracing is perhaps as old as the history of medicine. The first type of brace used was a splint, which was made of cloth and wood (Wirth & DeLee, 1990). Braces have evolved from intricate taping procedures to styles of bracing we more commonly identify. There are three different classifications of knee braces in use today. These categories are prophylactic braces, rehabilitative braces, and functional braces (Wirth & DeLee, 1990; Wojtys et al., 1996).

Prophylactic knee braces were introduced to reduce the number of knee injuries. They are also prescribed to athletes who have suffered a previous knee injury. Most prophylactic knee braces have side bar stiffness supplementation, no interference with activity, are able to adapt to different leg sizes, and are cost effective (France & Paulos, 1990).

Rehabilitative braces are normally used following ACL reconstructions to add protection to the newly reconstructed ligament (Wirth & DeLee, 1990). They are designed to provide early controlled motion. Rehabilitative knee braces usually have hinges, are durable, offer non-slip comfort, and ease of application (Cawley, 1990; Noyes, 1984; Wirth & DeLee, 1990; Wichmann & Martin, 1998).

Functional knee braces are the newest of these three categories. Lennox Hill was the first to design one for Joe Namath after his complaints of chronic knee instability in the late 1960's (Branch & Hunter, 1990; Wirth & DeLee, 1990). Functional knee braces are designed to reduce the amount of tibial translation occurring in the knee. The braces are lightweight and low profile for patient comfort.

There are two types of functional knee braces available to the athlete. The first type of functional knee brace is custom-fit model. They are usually recommended for highly competitive athletes because of their durability. They are also advantageous to those who have biomechanical or anatomical abnormalities in the knee, or who have leg girth measurements that are too large or too small for off-the-shelf knee bracing (France et al., 1990; Wirth and DeLee, 1990). A disadvantage of custom knee braces is the expense of the brace. Custom-fit braces are commonly $300.00 to $600.00 more expensive then off-the-shelf braces (France et al., 1990). Another disadvantage to these braces is their inability to change. If an athlete were to loose or gain weight, the knee brace must then be re-fit, which can be quite costly and time-consuming in itself (France et al., 1990; Wirth & DeLee, 1990).

The second type of knee brace is the off-the-shelf model. These braces are similar in structure and function to custom-fit braces, however they are considerably less expensive. They are designed to fit the majority of the population, and have decreased delivery time when compared to the custom-fit braces. The disadvantage to this type of bracing is the chance that an athlete's leg is too big or too small for the sizes of the brace (France et al., 1990).

Previous Research

The previous findings on knee bracing do not indicate toward any specific bracing trend. Some physicians still demand their patients' return to play with a functional knee brace. Other physicians are comfortable with the athlete simply performing a strong rehabilitation program, and then returning to competition without a brace. It is also difficult to discern whether knee bracing affects the athletes' performance.

Measurable differences in energy expenditure at low levels of exercise have been noted. Zetterlund et al (1986), noted a 4.58 percent increase in energy consumption when wearing a knee brace while running on a treadmill. Conversely, an unpublished study done at the Knee Brace Symposium, reported that an athlete wearing a carbon titanium knee brace that they had been using of six weeks showed no significant difference in their 40-yard dash, vertical jump, and figure eight patterns (Branch & Hunter, 1990).

In a study performed by Wojtys et al. (1996), muscular function was evaluated. Significance was found that athletes wearing derotational knee braces have reduced torque in isokinetic situations. The mean maximal torque during isokinetic knee extensions was decreased by

12-30 percent while wearing the knee brace (Wojtys et al., 1996). Houston and Goemans (1982) showed that the muscular strength of a braced leg was reduced by 30 percent.

Proprioceptive effects on the knee have also been studied. In a previous study, functional knee bracing did not have a significant proprioceptive effect on the knee (Cawley, 1990). In an ACL deficient knee, bracing did not restore proprioception to baseline levels (Beynnon et al., 1997).

The literature shows conflicting views. However, there is some effect on knee function with brace application. This information is not always available to the athlete before a bracing decision is made. The purpose of this study was to examine if a functional knee brace has any effect on the force production and stability of athletes so the athlete and physician can make a more informed decision regarding functional brace implementation.

Chapter Three

Subjects

All participants were recruited on a voluntary basis. Subjects were college-aged individuals ranging from 18 to 24 years old. There were two female and four male participants. All were off-season athletes at a NCAA Division II institution. Participants were healthy individuals with no history of significant lower extremity injuries. A significant injury was defined as an injury that kept the athlete out of practice for at least two days. The subjects all signed informed consent forms and a release for HealthSouth Western Hills Rehabilitation Hospital. The protocol was accepted through the Institutional Review Board at Marshall University (Huntington, WV).

Instrumentation

The knee brace that was used for the testing procedures was a DonJoy Legend (Smith & Nephew DonJoy Inc., Carlsbad, CA). The braces were new, however some usage of the braces was noted as the study went on. The knee braces were fit while the subjects were seated and their knee was passively flexed to a 45° angle. The pads of the knee brace were placed behind the midline of the knee, and the straps were attached in a step-by-step procedure as directed by the instruction pamphlet. The knee brace was re-adjusted for comfort as needed during testing. All braces were applied and adjusted by the investigator.

The Biodex Stability System (Biodex Inc., Shirley, New York) was used to record the stability information. Procedures were outlined in the owner's manual, and were followed accordingly. The computer software (Biodex, Version 3.1, Biodex, Inc.) is pre-programmed into a microcomputer in the unit, which calculates an overall stability index report. When using the Biodex Stability System, postural stability is defined as the degrees of displacement anterior-posterior and medial-lateral (Winslow, Mattacola, Sitler, & Kimura, 1998).

A standard Timex stopwatch was used to record times to the nearest hundredth of a second. The stopwatch was also used to time between separate tests and trials.

Johnson & Johnson coach tape was used to mark the start and finish lines. The tape was re-applied as needed during the testing procedures to ensure an accurate measurement from the start to finish line.

Methodology

Participants were recruited by way of a sign-up sheet in an administrative office at Ohio Valley College (Parkersburg, WV). Subjects were described the details of their participation at an informative meeting. They filled out the informed consent form (see appendix A) and a past medical history form (see appendix B) to address previous injuries. They also signed release forms (see appendix C) for HealthSouth at this meeting. They were fit with the DonJoy Legend knee brace to insure a proper fit for testing. They were dismissed from the study at this point if they had any previous significant injury to the lower extremity, or if their leg size did not make it possible for the brace to be properly fit.

The first day of testing was a familiarization period. The participants were asked to report to HealthSouth at an appointed time. Upon arrival, the participant drew one of four papers. This determined which leg would be tested and if the brace was applied. Following each test, the subject then drew one of the remaining papers. This process randomized which leg was tested, and if the brace was applied.

The testing session began with a four-minute ride on a stationary bike. This allowed time for increased blood flow to the lower extremity, and for the brace to adjust itself. Following the bike, the participants were given eight minutes to do manual stretching of the lower extremity. These included specific calf, hamstring, quadriceps, and adductor techniques, as well as a global stretching routine for the entire lower extremity.

Following the stretching period, the subject was instructed to jog for three minutes. At any time during this warm-up period, the brace was re-adjusted for the comfort of the participant.

All of the tests were performed with and without the brace on both legs. Following the warm-up period, the subject chose one number out of a box. The single leg hop test was represented by number 1, the timed hop was represented by number 2, and number three indicated the Biodex. The first test they performed was the first number they drew, and the second and third tests were determined by the second number they drew.

The first test was the single-leg hop. A measuring tape was secured to the floor with tape, and there was a starting line on the floor marked by a piece of white tape. The subject was instructed to stand on the leg to be tested, and to flex the opposite knee to ninety degrees without flexing their hip. Their hands were placed on their hips. They were instructed to perform this test with a maximal effort. Following the jump, measurements were recorded by noting the distance of the great toe from the starting line. The test was repeated two times with a one-minute break between tests. The measurements for the first day were discarded, as this was a familiarization period with the protocols.

The second test was the timed hop. There was a finish line six meters from the starting line. Both were marked with white tape. The subject was instructed to hop as quickly as possible to the line six meters in front of them. The positioning was the same as described for the single-leg hop. Timing started with the first movement, and was stopped when the great toe passed the finish line. Again, this was repeated two more times with a one-minute break between trials.

The final test utilized the Biodex Stability System. The subject was instructed to step onto the balance board, and their foot position was recorded into the machine. The subject was then asked to maintain their balance without using the handles located on the sides of the machine. When they were ready, the board was released, and they held their balance for 20 seconds. The system then generated a stability index. The test was repeated two subsequent times with a thirty second break between trials.

Following the tests, the subjects were given a ten-minute cool down period. This included stretching techniques for the lower extremity following the same stretches that were in the warm-up period. After this period, the subject was released from testing for the day, and was instructed to return the following day for testing.

The second day of testing repeated all of these procedures, however the recorded data was saved. The average of the three trials was used for statistical analysis. The data collection sheet is contained in appendix D.

The purpose of the study was to examine effects on an athlete's functional tests and stability index. The data from the second day was used to calculate these differences. Athletes need to be informed of any effect on their force production and balance prior to being given these braces.

Chapter Four

Results

The primary purpose of this study was to determine if a functional knee brace had any effect on force producing tests as well as postural stability in healthy athletes. A paired T test was utilized using an alpha level of .05 to show significance.

Data Collection

The trials for the single leg hop were measured to the nearest inch. The timed hop was recorded to the nearest hundredth of a second. The stability index was calculated with measurements to the nearest hundredth. The average of the three trials was used for calculations in a matched T-test.

The statistics were calculated by using the Statistical Analysis System (SAS) through Marshall University. This is a statistical program through the HOBBIT system that analyzed the testing data. Separate paired T-tests were run to calculate means and standard deviations for the single leg hop, timed hop, and stability index.

The single leg hop distance was significantly affected by the functional brace. The T value was 2.71

($p<.05$). The mean distance with the brace was 73.18 inches and without the brace it was 75.60 inches. Standard deviation with the brace was 9.04 and without the brace was 9.59.

The timed hop was also significantly affected by wearing a functional knee brace. The T value was 3.22 ($p<.05$). The mean time with the knee brace was 1.73 seconds and without the brace was 1.59 seconds. The standard deviation with the brace was 0.24 and without the brace was 0.19.

The stability index was not significantly affected by the knee brace. The T value was .275 and $p=.7886$. The mean with the brace was 3.67 and without the brace was 3.61. Standard deviation with the brace was 1.18 and without the knee brace was 1.35. There was no sign of a trend as to whether the knee brace would affect the stability index if more subjects were tested.

Data Interpretation

The functional knee brace significantly affected the subjects' single leg hop for distance and their timed hop for speed. The single leg hop was reduced by an average of 2.42 inches while wearing the brace. The timed hop was reduced by an average of .14 seconds while wearing the knee brace.

The alpha level or P-value was determined at the .05 level of significance. This means that there was less than a .05 chance that the results were determined by error.

The significance shown by the data led to a rejection of null hypothesis number one. This hypothesis stated that there would be no difference in the single leg hop test while wearing the knee brace.

Null hypothesis number two was also rejected. This stated that an athlete's timed hop would not be affected by a functional knee brace.

There was no significance found on the stability index of athletes while wearing the knee brace. Because of this, there was a failure to reject null hypothesis number three, which said that there would no difference in the stability index of athletes while wearing the functional knee brace.

This data reveals that a functional knee brace significantly negatively affects an athlete's single-leg hop test and timed hop test. This information should be readily available to athletes whose doctors chose to prescribe these braces. They should be aware that the brace may negatively affect their force production.

Chapter Five

Discussion

Functional knee braces have been used following anterior cruciate ligament injuries since they were developed by Lennox Hill for Joe Namath (Branch & Hunter, 1990; Wirth & DeLee, 1990; Wichmann & Martin, 1998; Wojtys et al., 1996). Competitive athletes need to be informed of the effects on their force production and speed before returning them to competition with a functional knee brace following injury. Previous studies have shown conflicting information whether these knee braces help or impede and athletes performance.

Prior studies support these findings on the effect on speed testing. In Wojtys et al. (1996), athletes' mean maximal velocity on a stair run was decreased when wearing a functional knee brace. They also examined maximal torque production. Knee bracing also reduced torque production during isokinetic situations in the Wojtys study.

Previous studies have also demonstrated that bracing affects distance jumps. Juris et al. (1997) showed that unconstrained motion resulted in longer maximal hops during single leg hop testing. This may be due to the effect on muscles while wearing the brace. Styf, Lundin, & Gershuni (1994) demonstrated that a knee brace elicited muscle fatigue faster than an unbraced knee. There has been documentation that knee muscle strength affects the single leg hop test (Sekiya, Muneta, Ogiuchi, Yagishita, & Yamamoto, 1998). Muscular strength affects the results of functional testing and is also an important factor in the return to competition decision as it protects the ACL from damage (Aune et al., 1997; DeVita, Lassiter, Hortobagyi, & Torry, 1998; Nordt, Lofti, Paymaun, Plotkin, & Williamson, 1999; Risberg et al., 1999; Rosene & Fogarty, 1999; Rozzi, Lephart, Gear, & Fu, 1999). Therefore, the single leg hop is a significant determinant in the return of an athlete to competition.

The findings on stability did not differ from the majority of previous research. Previous studies have focused on injured athletes, whereas this study was performed on uninjured subjects. Beynnon et al. (1999) reported that a functional knee brace did not restore proprioceptive awareness through joint position testing. However, the stability of athletes varies from the proprioceptive techniques of joint position awareness. Few studies have been performed using the Biodex Stability

System, so there was little research to follow (Schmitz & Arnold, 1998; Winslow, Mattacola, Sitler, & Kimura, 1998.)

Future Research

Future research needs to be performed utilizing off-the-shelf knee braces on previously injured athletes that have had their ACL reconstructed. Also, future research should compare off-the-shelf to custom-fit braces to calculate any differences in these tests between the two braces.

These results need to be reproduced on injured knees to note if the findings are consistent. Additionally, future research should increase the number of subjects and test different ages of the population for the potential to generalize. Gender differences should also be examined, as this study was unable to note any specific differences due to a small N. Future research should also focus on the stability index of injured knees as there is little information regarding this area of study available. This study was able to show significant statistical evidence that a functional knee brace has an effect on force production and speed of a healthy athlete.

Conclusion

From this study, conclusions were made that functional knee bracing significantly negatively affected athletes' single leg hop for distance and timed hop. There was no significance on the stability index while wearing the knee brace. Athletes should be informed that while they may be gaining mechanical superiority in stabilization, they may be sacrificing force production and speed. Every second counts to competitive athletes, and they may be negatively affected by wearing a functional knee brace for stabilization.

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Appendix A

Heidi E. Moran, ATC

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY ENTITLED:
The effects of a functional derotational off-the shelf knee brace on the stability, single leg hop, and timed hop test on NCAA Division II collegiate athletes

Introduction:

I am invited to participate in a research study, which will take place at Ohio Valley College and HealthSouth Western Hills Rehabilitation under the protocols set forth by Marshall University. All individuals who volunteer to participate in the study must know that: a) participation is entirely voluntary; b) I may not personally benefit from the results of this study, but results of this study may benefit people in the future; c) I may end my participation in the study at any time without penalty.

The specific facts of this study are described in the attached research protocol. A simplified summary of this information is given below. If I have any questions, I may ask the person who has discussed this study with me.

Nature of the Study:

I will be asked to perform three different tests. The first two will be completed in the Snyder Activity Center. The first test is a single leg hop test for distance. I will be instructed to do a single jump for distance. I will perform this test with and without a knee brace on both legs. The second test is a hop test for time. I will be asked to again perform a single leg jump, however this time, I will have to jump from a starting line to a line six meters from the start and then back to the beginning line. The amount of time it takes me to perform this test will be recorded. This test will be performed on both legs, with and without the knee brace.

The last test will be performed at HealthSouth. This is a balance test. I will be asked to step on to an electronic balance board and stand on one leg. I will be instructed to hold this position for 20 seconds. There will be a 30-second break on between each test. I will be asked to perform this test six times on each leg, three trials with the knee brace, and three trials without the knee brace. At this time, I will be released from testing for that session. I will have to return on two subsequent times to repeat these procedures, for a total of 3 days of participation, approximately 45 minutes each session.

Risks:

The potential risks are muscle cramping from the knee brace and muscle strains due to the exercise. To alleviate these risks, there will be a warm-up period for stretching, and the tester will readjust the brace following the warm-up period. There is also a risk of losing balance on the balance board. To eliminate this risk, a guiding system from Biodex will be implemented. Chaffing of the skin may occur from the brace, however this can be counter-acted with pre-wrap where the brace is rubbing.

Research-Related Injury:

In the event that my participation in this study results in illness or injury, I or my insurance company and/or other hospital provider will be asked to pay for costs of treatment. The investigators, Marshall University, Ohio Valley College, or HealthSouth Western Hills Rehabilitation Inc. will provide no other compensation, financial or otherwise.

Who to Contact:

1. If I have any questions regarding this study, I may contact Heidi E. Moran, ATC at (304) 485-7384 x5004.
2. 2. If I have any questions regarding research subjects' rights, I may contact the IRB chairman at (304) 696-7320 during regular working hours (8:00am - 4:00pm).

Subjects initials/date

Witnesses initials/date

Heidi E. Moran, ATC

CONFIDENTIALITY:

I understand that confidentiality of my records will by maintained and that my identity on research forms, presentations and in public articles will not be revealed. I understand that the Marshall University IRB, the Food and Drug Administration, or other appropriate Federal or State Agencies may inspect the records in the ordinary course of carrying out their functions. Except as noted above or as may be requires by law or hospital policy, my identity will remain confidential.

I will not receive any payment for my participation in this study.

This is to certify that I have read the explanation of the above research study and agree to participate in the work as described in this protocol and consent form.

Subject's name (please print)

Subject's signature Date

Witness's name (please print)

Witness's signature Date

APPENDIX B

Past Medical History Form

1. Have you suffered a hip, knee, or ankle injury in the past six months?

   Yes No

2. If yes, did that particular injury keep you out of practice or competition for at least two days?

   Yes No

3. Do you currently wear knee or ankle braces during competition or practices?

   Yes No

4. Do you have any other condition, such as heart problems, that would hinder your performance in this study?

   Yes No

5. If yes to question #4, please explain.

6. Do you feel that you are at healthy and can perform optimally at this time?

   Yes No

APPENDIX C

RELEASE AND WAIVER

In consideration of the undersigned being permitted to use the facilities and equipment of HealthSouth Corporation ("HealthSouth") and its affiliates, the undersigned, individually and on behalf of the undersigned's heirs, representatives and next of kin, agrees to: (i) release, waive and to indemnify and hold harmless, HealthSouth and its employees and affiliates from all loss, expense, and liability for injury, death, or damage to the person or property of the undersigned, whether caused by the negligence of HealthSouth, its employees or affiliates, or otherwise, while using HealthSouth's facilities or equipment; and (ii) assume full responsibility for risk of injury, death or damage to the person or property of the undersigned, whether caused by the negligence of HealthSouth, its employees or affiliates, or otherwise, while using HealthSouth's facilities or equipment. All participation and use of the facilities shall be at the undersigned's own risk, and the undersigned hereby assumes any and all risks associated with such use.

The undersigned acknowledges that no oral or written statements or agreements contrary to this document have been made to the undersigned and that this document supersedes any and all prior statements and agreements with HealthSouth. This document may only be changed in writing executed by HealthSouth.

The agreements in this document shall be continuing and shall not terminate without the prior written consent of HealthSouth.

The undersigned acknowledges that undersigned is aware of the proper use of the equipment, understands the possible risks and dangers involved in using the facilities and equipment at the facilities and, and has read, understands and voluntarily signs this document.

Signature ______________________________

Print Name ______________________________

Date ______________________________

Witness ______________________________

APPENDIX D

Subject__________

Date_____________

	Single-Leg Hop	Timed Hop	Stability Index
Trial 1			
Trial 2			
Trial 3			
Average			

Abstract

Functional knee braces are often used by athletes following an injury to their anterior cruciate ligament (ACL). However, few athletes are given information as to whether the knee brace will hinder their ability. The purpose of this study was to examine the effects of a functional derotational knee brace on the single leg hop for distance, timed hop, and overall stability index of athletes. Twelve healthy knees were tested with and with out an off-the-shelf DonJoy Legend knee brace. A matched T-test showed a significant difference between the single leg hop ($T = 2.71$, $p < .05$) and timed hop ($T = 3.23$, $p < .05$) while wearing the knee brace. There was no significance found when examining the stability index while wearing the brace. It was concluded that the functional knee brace decreased the distance of a single leg hop and increased the time it took to perform a timed hop.