Quantitative Analysis of Functional Knee Appliances in Controlling Anterior Cruciate Ligament Deficient Knees

By

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ABSTRACT

The purpose of this investigation was to evaluate and compare the efficacy of three functional knee braces in stabilizing anterior cruciate ligament (ACL) deficient knees. Brace effectiveness was established as the ability to control joint range of motion during active and dynamic activity. The subject sample consisted of eighteen males and females with a unilateral ACL deficiency.

This study consisted of two parts; the first involving twenty-four braced knees. A completely randomized design involving one independent variable with three levels was used. The second part consisted of three subjects, each having all three types of braces. A randomized block design with repeated measures was used, with each subject acting as a block.

The criterion variables consisted of the ability of each brace in controlling internal rotation and knee extension during active movement and knee extension during a high velocity activity (dynamic task). Finally, total displacement of the knee brace during a running test was also evaluated.

Analysis consisted of a one-way Anova for each of the criterion variables. The results of the first part of the study demonstrated significant differences ($p<.05$) between the efficacy of the three braces for control of knee extension during active movement , knee extension during a dynamic task and brace migration during a running task.

There was no significant difference between the efficacy of the three braces in controlling internal rotation during active movement. However , the second part of the study demonstrated significant differences among braces in brace migration only ($p<.05$).

RESUME

Cette etude a pour but d'evaluer et de comparer l'efficacite de trois ortheses fonctionelles pour le genou offrant plus de stabilite aux dechirures de ligament croise anterieur (LCA). L'efficacite d'une orthese se definit par sa capacite a controler l'amplitude articulaire durant un mouvement actif et dynamique. L'echantillonnage de sujets compte dix-huit hommes et femmes avec une difference unilaterale du croise anterieur (LCA).

Cette etude se divise en deux parties, la premiere implique vingt-quatre genoux avec orthese. Une situation entierement au hasard utilisant une variable independante avec trois niveaux. En deuxieme lieu, chacun des trois sujets portera trois ortheses differentes. "A randomized block design" avec mesures repetees est utilise avec chaque sujet agissant comme un bloc.

Les variables de criteres consistent en la capacite de chaque orthese a controler la rotation interne, et l'extension du genou durant un mouvement actif et extension du genou pendant une activite a haute velocite (manoeuvre dynamique). Finalement, le deplacement total du genou a aussi ete evalue lors de la course.

RESUME (continued)

L'analyse consiste en un sens "anova" pour chaque variable choisie. Les resultats de la premiere section de l'etude demontre une difference significative ($p < .05$) entre l'efficacite de trois ortheses pour chacun des criteres evalues a l'exception de la rotation interne. Toutefois la deuxieme partie de l'etude demontre des differences significatives parmi les ortheses a l'epreuve, concernant la migration de l'orthese, seulement ($p < .05$).

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Chapter 1

INTRODUCTION

One of the most common injuries in sports today is a tear of the anterior cruciate ligament of the knee joint. Not only is this considered a serious injury but it can also be a long term debilitating injury (Noyes, McGinniss, & Mooar, 1984). Athletes who sustain this type of injury are faced with the choice of either having the injury surgically repaired or following a conservative method of treatment. The non--surgical approach involves rehabilitative therapy and often the use of a functional knee orthosis is recommended in hopes that the athlete can return to their respective sport with less risk of re-injury. However, controversy exists concerning the usefulness and effectiveness of knee braces. In 1987, the American Academy of Orthopaedic Surgeons (Akeson, Frank, Amiel, & Woo, 1985) issued a policy statement indicating that functional knee braces aid in the control of unstable knees by limiting anterior translation of the tibia on the femur. It was also indicated that under high forces this mechanism of control was no longer valid (Akeson et al., 1985). And yet, other studies suggest that knee braces do play a role in stabilizing ACL damaged knees during dynamic activity (Coughlin, Oliver, & Berretta 1986; Colville, Lee, Ciullo, 1986; Nocholas, 1983).

To date very little research has been reported concerning the evaluation of the efficacy of a knee orthosis during dynamic activity. The absence of an objective method of identifying whether a brace is in fact effective has proved a dilemma to physicians, trainers and athletes who are left questioning whether the brace they are using is going to protect the knee from further injury. Research in this area is necessary in order to improve existing orthotic technology and design. Therefore, the purpose of this research was to determine which characteristics of the brace design were important in providing knee stability during active and dynamic movement and how this mechanism of control was established. Once the criteria for measuring efficacy was determined it was then used as a basis for comparison of three commercially available functional knee braces.

1.1 Nature and Scope of the Problem

Functional knee braces are frequently prescribed with the goal to improve stability of an anterior cruciate ligament (ACL) deficient knee and to prevent re-injury of that same knee. Knee braces have been evaluated under conditions of low passive loads (Bassett & Flemming, 1983; Hoffman, Wyatt, Bourne, & Daniels, 1984; Knutzen, Bates, & Hamill, 1984) where they have been shown to be effective in controlling anterior translation of the tibia on the femur and internal rotation, two movements which render the ACL deficient knee unstable. The (Akeson et al., 1985) has stated that this control mechanism does in fact help stabilize the knee joint during passive, low load activity. However, functional knee braces were designed to work during dynamic activity. It is under these conditions that the efficacy of the knee brace must be evaluated. The AAOS seriously questions the ability of the knee brace to stabilize the knee joint by controlling anterior translation during dynamic activity. And yet, several studies indicate that there is indeed a mechanism functioning during dynamic activity which helps to stabilize the ACL deficient knee (Colville, & Ciullo1986; Kennedy, Weinberg, & Wilson, 1974; Lysholm, & Gillquist, 1982). This study postulates that the key element for effective stabilization during dynamic activity is control of joint range of motion and that the effectiveness of this mechanism is dependent on the actual fit of the brace.

The proposed theory of gaining knee stability by controlling range of motion is based on the fact that the ACL deficient knee is rendered more unstable when placed in positions of extreme internal rotation where excessive stretch is placed on the ligament and knee extension where the tibia is more prone to subluxate anteriorly and then relocate (Knutzen et al., 1984; Hoffman et al., 1984; Bassett & Flemming, 1983). This later phenomenon is known as the pivot shift and is prominent in the last few degrees of knee extension due to the strong pull of the quadriceps muscle coupled with the poor counter pull of the hamstrings muscle group (Noyes et al., 1984; Solomonow, Baralta, & D' Ambrosia, 1989; Gurtler,Stine,& Torg, 1987; Fetto & Marshall, 1979).

Since dynamic activity often involves the transfer of high magnitude forces through the knee joint (Vardaxis, 1988) the mechanism of controlling anterior translation directly becomes ineffective (Beck, Drez, Young, Cannon, & Stone, 1986; Bassett & Fleming, 1983). However, by limiting the extent of internal rotation in the knee joint and by preventing full knee extension, a secondary method of stabilizing the knee joint can be established and this mechanism can provide much needed stability during dynamic activity.

This study investigated the functional characteristics of three knee braces using active and dynamic tests. This research was based on the following two premises:

1) In order to determine and evaluate the function of the knee brace the characteristics of an ACL deficient knee must be understood. The following are characteristics of a damaged ACL:

a) an increase in anterior translation of the tibia on the femur.

b) an increase in internal rotation of the tibia on the femur.

c) an increase in knee instability as the knee joint approaches full knee extension (Ahmed, Hyder, Burke, & Chan ,1987; Lipke, Janecki, Nelson, McLeod, Thompson, Thompson, & Haynes, 1981; Daniel, Malcolm, Loose, Stone, Sachs, & Burks, 1985; Markolf , Shapiro, Gorek,& Kalo, 1990).

In vitro studies by Ahmed (1987), Lipke (1981) and Fukubayashi (1982) all demonstrate that the primary function of the ACL is to control anterior translation and internal rotation of the tibia on the femur. Subsequently, damage to the ACL results in an increase in anterior translation and internal rotation. The increased laxity renders the knee joint unstable resulting in an interference of the transfer of energy from the tibia to the femur during dynamic activity (Marquette, 1988).

Ahmed (1987) and Markolf (1976) both stated that the combination of translation and rotation seen in ACL deficient knees result in a medial shift in the transverse axis of the knee joint causing the lateral tibial plateau to subluxate. This produces the commonly described sensation of the knee " giving way ". Both Markolf (1976, 1990) and Ahmed (1987) stated that this mechanism of instability is most prevalent in the last degrees of knee extension.

2) Functional knee braces were designed to limit the deficiencies of an ACL injured knee using the following structural devices:

a) a four point pressure system formed by the straps and moldings of the brace to limit anterior translation (Marquette, 1988).

b) a tibial strap, bar or mold which by nature of its shape and approximation to the tibia limits internal rotation of the tibia on the femur (Coughlin et al., 1986;Nicholas, 1983).

c) an extension stopper mechanism in the brace hinges and a posterior popliteal strap to limit full knee extension (Marquette, 1988).

In summary the efficacy of the functional knee brace in limiting ACL deficiencies is dependent on two proposed factors:

a) The ability of the brace to control range of motion of the knee joint (specifically internal rotation and extension) during active and dynamic movement.

b) The general fit of the brace as measured by the amount of displacement of the brace during dynamic activity (Lew, Patrnchak, Lewis, &Scmidt, 1982; Coughlin et al., 1986; Walker, Kurosawa, Rovick, & Zimmerman, 1985; Shafer, Russ, Patrnchak , & Tarr , 1988).

The orthosis must be anchored to the skin adequately so that the limitations imposed on the dynamics of the brace as designed by the manufacturers (eg. extension stopper) can be transmitted to the skeletal system resulting in control of the femur on the tibia. Lew (1982) suggested that the displacement of the knee brace could disrupt the normal phase of knee motion and could impede the actual function of the knee brace which is, to stabilize the knee joint. Lew also stated that the optimum position of the hinge of the brace is when it is aligned as well as possible with the axis of rotation of the knee joint. Displacement of the hinge from this position will impede the function of the brace. Walker (1985) and Shafer (1988) supported these findings and concluded that the function of the brace hinge was to account for axial rotation and anterior/posterior translation of the knee joint. Any migration of the hinge would render the brace less effective.

Thus, it can be postulated, knee appliances are in part designed to provide protection to the knee joint by controlling the range of motion of the knee. In doing so the brace prevents the joint from applying excessive forces to the deficient ligament by preventing the knee from attaining a weak or unstable posture. Furthermore, the effectiveness of the brace is enhanced by proper fit.

The purpose, therefore, of this investigation was to establish whether three different yet very popular functional knee braces were effective in controlling the range of motion of the knee joint under active and dynamic conditions and if this was related to the general fit of the brace.

1.2 Objectives

Criterion variables most likely to accurately evaluate the efficacy of the knee orthosis can be determined by considering the factors which reflect the function of the ACL as well as the factors which characterize knee orthoses. The knee brace is designed to control increased internal rotation characteristics of ACL deficient knees. Therefore the difference between internal rotation of the ACL deficient knee and active internal rotation of the braced ACL deficient knee reflect the efficacy of the knee orthosis in controlling range of motion. Secondly, the knee braces being evaluated in this study all have extension stoppers built into their hinge joints to prevent the knee from going into full extension. In ACL deficient knees this is a position of extreme vulnerability since the tibia is more likely to subluxate or shift during this part of the range and thus the knee is more unstable and more prone to injury. The difference between active extension of the ACL deficient knee and active extension of the braced ACL deficient knee was used as a criterion variable to evaluate the efficacy of the knee orthosis in controlling range of motion. In addition, a functional evaluation of this important characteristic of knee braces was performed using a dynamic task. The subject was asked to perform an instep straight soccer kick with the ACL braced deficient knee. The difference between the knee joint angle and the brace angle (brace/ joint congruency) was measured to evaluate the efficacy of the orthosis in preventing knee extension during high velocity dynamic activity.

Finally, the precise fit of the knee brace in relation to the actual knee joint was evaluated. The literature strongly supports the fact that the fit of the brace has a direct effect on the function of the orthosis (Shafer et al., 1988; Walker et al., 1985). The evaluation of the function of the knee brace determines the efficacy of that knee brace in ultimately providing stability to the ACL deficient knee. Therfore, no matter how well designed a brace is, no matter how effective it is in controlling the range of motion, if it does not fit properly it will prove to be ineffective during dynamic activity.

Two different measurements were used to evaluate brace fit. First, the total amount of displacement of the brace hinge during a ten minute run on the treadmill was evaluated and used as a criterion variable. Second, the distance between the tibial mold and the tibia was measured. The purpose of the plastic mold on the tibia is to control internal rotation and tibial translation and thus it must be in close contact with the tibia throughout the range of motion of the knee joint. In order to evaluate this as a component of brace fit and use it as a criterion variable the following three measurements were taken: the distance between the brace and the center of the medial tibial plateau, the distance between the brace and the center of the patellar tendon and the distance between the brace and the center of the lateral tibial plateau. These measurements were taken at four different flexion angles (15, 30, 60 & 90 degrees) in order to reflect the fit of the brace throughout the range of motion of the knee joint.

1.3 Criterion Variables

The following criterion variables were chosen to determine the efficacy of a functional knee brace during dynamic activity:

Brace function / control of range of motion:

1) Control of internal rotation = (active internal rotation of the ACL deficient knee) - (active internal rotation of the braced knee).

2) Control of extension = (active extension of the ACL deficient knee) - (active extension of the braced knee).

3) Brace/ knee joint congruency = relative brace angle - relative knee angle during dynamic activity.

Brace fit:

1) Total brace displacement during the running task = (vertical displacement of the hinge) + (horizontal displacement of the hinge).

2) Approximation of the tibial mold = (medial distance) + (central distance) + (lateral distance).

1.4 Hypotheses

The hypotheses for this study are as follows:

1) There will be no significant differences among the values for internal rotation control for all three braces.

2) There will be no significant difference among the values for extension control for all three braces.

3) There will be no significant difference among the values for Brace/ knee joint congruency for all three braces.

4) There will be no significant difference among the values for brace displacement during the running task for all three braces.

1.5 Limitations

Even though all precautions were followed to decrease error in this study certain limitations still exist.

1) Inherent errors due to the use of cinematography data (camera movement, lens distortion).

2) The effects of muscular forces on knee stability and brace function were not taken into account.

3) The braces were neither fitted by, nor manufactured by the same individual for all cases.

4) Isolated tears of the ACL do not occur frequently and are usually associated with damage to secondary structures which may affect the function and characteristics of the knee joint (Noyes et al., 1984).

The effect of muscular activity during the testing procedure was not measured. Although, recent research by Howel (1990) indicates that muscular activity plays an important role in stabilizing the knee joint, it was not the purpose of this study to evaluate joint stability due to muscle activity but instead to evaluate brace function and how this related to joint stability. Intra- subject differences in muscular activity did not effect the measurements taken during the testing procedure. Although braces were not fitted by the same individual or manufactured by the same person, a licensed orthotist took the measurements thus providing standardization and consistency. Since this entire procedure occurred randomly and was standardized there was no need to be concerned about this variable confounding the results.

Finally, the extent of a knee injury should not effect the values of the criterion variables being measured in this study since the controlling factor of the brace is not dependent on the level of injury for the measurements taken in this study. All subjects in this study had complete ruptures of the ACL.

Further control of all the above limitations was achieved by the fact that some subjects were tested with all three braces and their results were compared with the individual brace groups.

1.6 Delimitations

The following delimitations are found in this study:

1) Subjects were between the ages of eighteen and thirty-five.

2) Only subjects with ACL deficient knees were studied.

3) All injuries were a minimum of 6 months old.

4) Only three functional knee braces were evaluated.

Chapter 2

REVIEW OF LITERATURE

2.1 Introduction

This chapter examines the deficiencies of an ACL injured knee and determines how to best control for the dysfunction in order to improve joint stability.

Functional knee braces have been designed in an attempt to lessen the degree of disability found in ACL deficient knees. The components and design of the knee orthosis act to control the factors which cause instability in the knee joint and which ultimately increase the potential for re-injury. This chapter examines the logistics behind knee brace designs and why their control of knee range of motions is an important determinant of brace efficacy.

Another important factor to be considered when studying knee braces is how well does the brace fit the anatomical contours of the specific knee joint. This chapter examines the work of several authors (Lew et al., 1982; Walker et al., 1985; Shafer et al., 1988) who have indicated the importance of minimizing brace migration in order to optimize brace function and joint stability.

Finally, a review of previous research in the areas of static and dynamic testing are presented in order to establish the relevance of evaluating brace efficacy based on joint range of motion control and brace fit.

2.2 Characteristics of an ACL Deficient Knee

In order to truly comprehend the purpose and function of a knee orthosis it is important to have a clear understanding of the role of the ACL in knee stability. Many in-vitro studies attempt to ascertain the function of the ACL while under static or quasi-static loading. These studies are designed to demonstrate the biomechanical functional characteristics of joint structures (ligaments, menisci and capsule) by removing the effect of each structure one at a time and measuring the impact on joint stability.

The ACL is a fibrous band originating from the posterior medial surface of the lateral femoral condyle and inserting into a wide depressed area in front of and lateral to the anterior tibial spine. When the knee is extended the ACL is flat and when the knee is flexed the ACL twists on itself and the posterior cruciate ligament (PCL). More specifically the ACL is comprised of three separate sections: the anterior fibres which are taut in extension, the medial fibres which are taut in internal rotation and the posterior fibres which are taut in flexion (Wang, Walker, & Wolf , 1973; Smillie, 1970; Girgis, Marshall & Monajem, 1975).

2.2.1 Anterior Translation

One of the functions of the ACL is to prevent anterior translation of the tibia on the femur. Butler et al., (1980) demonstrated that the ACL was the primary restraint against anterior translation, providing 86 % of the total resisting force. Studies by Ahmed (1987), Lypke (1981) Daniel (1985), and Fukubayashi (1982), all further demonstrated that the primary function of the ACL is to control anterior translation of the tibia on the femur. Markolf, Mensch, & Amstutz (1976) and Fetto et al., (1979) concluded that a damaged ACL resulted in an increase in anterior displacement especially in extension. This displacement in turn causes a disruption of the alignment of the femur and tibia which interferes with proper transfer of energy through the knee joint resulting in further instability, especially during high intensity dynamic activities (Butler, Noyes, & Grood, 1980; Crownshield, Pope, & Johnson, 1976). Therefore, the ability of the brace to control or limit extension results in improved stability and more effective function during dynamic activity. Control of knee extension by the orthosis improves the efficacy of that particular brace and reduces the risk of re-injury (Blacharski & Somerset, 1975).

2.2.2 Internal Rotation

The second function of the ACL involves limitation of excess internal rotation. Piziali, Rastegar, Nagel, & Schurman (1980) reported that the cruciate ligaments resisted internal rotation of the tibia by winding around themselves. Rotatory motion can be related to the axis of rotation between the femur and the tibia and the movements generated about this axis by the ligamentous structures.

Gollehon , Torzilli, & Warren (1987) reported that the ligaments in an intact knee acted to maintain the equilibrium in the joint. When a ligament is damaged, the balancing forces exerted by the remaining structures will change as the knee moves to a new position of equilibrium to compensate for the loss. Lipke et al., (1981) and Kennedy & Fowler (1971) support the idea that the function of the ACL is to prevent internal rotation of the tibia on the femur. Lipke et al., (1981) stated that the role of the ACL is to maintain the position of the center of rotation of the tibia in the transverse plane. If there is damage to the ACL the axis will shift medially, and under these conditions, excessive internal rotation will result. A medial shift of the axis will provide a longer lever arm for the applied rotary forces from the lateral collateral ligament resulting in anterior lateral subluxation of the lateral tibial plateau and increased internal rotation. Noyes et al., (1984) described the phenomenon as a ("pivot shift") subluxation of the tibia which can occur during static testing (pivot shift test) and is often reproduced in dynamic setting during movements involving jumping, cutting and deceleration.

2.2.3 Extension

The position of full knee extension becomes a position of increased instability in an ACL deficient knee. Ahmed et al., (1986) stated that with an increase in knee extension there is an increase in anterior displacement of the tibia on the femur. Markolf et al., (1976) also demonstrated that a damaged ACL resulted in an increase in anterior displacement especially in extension. Cabaud & Rodkey (1985) stated that the ACL has a unique function in providing stability as the knee joint extends, allowing the tibial plateau to track on the longer medial femoral condyle, thus forcing the tibia into external rotation with a screw-home mechanism. A deficient ACL knee will alter the position of the tibial plateau resulting in increased internal rotation and decreased stability.

The previously described phenomenon of the "pivot shift" has been biomechanically explained by the fact that upon heel strike (knee extension) during a strong quadriceps contraction with the knee in extension, the quadriceps muscle pulls the tibia forward so that it rests in a subluxated position and when the knee is flexed between 20 and 40 degrees the iliotibial band tightens over the lateral tibial plateau causing a reduction of the tibia. The position of knee extension is further compromised by the fact that the hamstring muscles, which functionally are capable of limiting anterior drawer, are at a mechanical disadvantage and thus have little effect on the joint stability at this point (Noyes, et al., 1984; Solomonow et al., 1989; Gurtler et al., 1987 & Fetto et al., 1979). The AAOS has stated that knee braces under dynamic conditions are incapable of controlling anterior translation and thus the best means of controlling the excessive movement is by avoiding positions where it is most prevalent.

2.3 Characteristics of a Functional Knee Orthosis

The purpose of a functional knee orthosis is to control laxity in an unstable knee and to protect the knee from further damage or injury. Although it is impossible for a brace to mechanically substitute for the function of the ACL it must compensate for the deficiencies in an ACL injured knee (Marquette, 1988).

During dynamic activity the purpose of the ACL is to maintain femoral and tibial articular surfaces in correct alignment so that joint configuration can provide stability when loads are applied (Lipke et al., 1981; Hsieh & Walker, 1976). In an ACL deficient knee, the joint surfaces are not aligned due to increased laxity and therefore a knee orthosis which can control anterior translation and internal rotation of the tibia on the femur will increase the stability of an ACL deficient knee by improving joint alignment. Butler et al., (1980) concluded that in ACL deficient knees secondary restraints may block clinical laxity tests but in time they stretch out and cannot provide stability under higher functional activity forces. Therefore, the knee orthosis must control the laxity or instability present in the knee for the joint to accommodate the large forces found during dynamic activity. Passive testing of knee laxity in a braced knee may result in the conclusion that a brace is effective when in fact it is the secondary structures of the knee that are improving the stiffness and not necessarily the brace. By testing the brace under high load functional activities the compensation from secondary structures can be reduced (Buttler et al., 1980).

2.3.1 Control of Anterior Translation

The difficulty with controlling anterior translation of the tibia on the femur arises from the fact that a small displacement (8-10 mm) must be controlled while the knee joint is subjected to hundreds of newtons of force (Marquette, 1988). Brace manufacturers use a four-point pressure system in an attempt to limit anterior translation. This involves placing the pressure through elastic or non-elastic straps on the distal posterior femur and the proximal anterior femur to produce one lever system and applying pressure on the anterior proximal tibia and the posterior distal tibia for a second lever system. The result of this lever system is to promote the normal geometric alignment of the tibia and femur so that forces can be transferred from the tibia to the femur. In healthy knees this transfer occurs in part through the function of the ACL (Marquette, 1988; Butler et al.,; 1980).

2.3.2 Limitations of Internal Rotation

A further means of improving knee stability is to control the amount of internal rotation occurring at the knee joint. One of the characteristics of an ACL deficient knee is an increase of internal rotation of the tibia on the femur since anatomically the ACL acts as a restraint to internal rotation (Gollehon et al., 1987). The resulting increase in internal rotation of ACL deficient knees leads to an anterior subluxation of the lateral tibial plateau often presented as a 'pivot shift' or " giving way " sensation (Lipke et al., 1981; Noyes et al., 1984) resulting in an increase in knee instability. By controlling internal rotation of the tibia on the femur, the knee brace provides improved stability of the joint. Rotational control was maintained in the braces evaluated in this study by close-fitting plastic pre-tibial shell or bar (Coughlin et al., 1986), lateral leg pads and derotation straps (Nicholas, 1983). Finally, the sliding axis of motion found in the hinge of each brace, theoretically, corresponds to the axis of rotation of the knee and helps control rotatory instabilities.

2.3.3 Limitations of Knee Extension

The final means of improving knee stability is by limiting knee extension. As previously discussed, when the ACL deficient knee approaches full extension the amount of anterior translation or anterior laxity increases resulting in joint mal-alignment and thus further instability (Markolf et al., 1976; Ahmed et al., 1986). The position of knee extension is also the starting point for the development of the phenomenon of the pivot shift which once again renders the knee unstable and ultimately leads to a less functional joint. Therefore, it is extremely important for a knee brace to prevent complete knee extension during dynamic activity otherwise, the joint is placed in a vulnerable, unstable position which could result in re-injury (Hughston & Norwood, 1980). This limitation of knee extension is achieved first with an extension stopper which prevents the knee from going beyond 10- 15 degrees of extension and second, by a posterior strap which maintains the subject's leg in the orthosis and thus prevents the joint from fully extending.

2.3.4 Review of Three Functional Knee Braces

In this study three commercially available functional knee braces, which are representative of the existing market, were evaluated. These included the following: the A-C brace, the Lennox Hill brace and the Medicus brace. Coughlin et al., (1986) and Beretta, Charuest, Berretta, & Berretta (1985) described the A-C brace as being a polycentric joint with an extension stopper and a lateral tibial mold to decrease abnormal tibial rotation and lateral tibial subluxation. The A-C orthosis is made from a plaster cast taken of the flexed leg at approximately 30 degrees and the foot completely dorsiflexed. All orthoses have a 15 degree extension stopper which prevents the knee from extending completely. The plastic pre-tibial shell helps to suspend the orthosis and provides a distribution of pressure over the anterior tibia as the orthosis reaches its extension stop and thus prevents possible pain from tibial impingement. Rotational control is obtained by the shape and close fit of the plastic pre-tibial shell. The posterior strap maintains the subject's leg inside the orthosis and prevents the joint from extending beyond 10-15 degrees of flexion.

The Lennox Hill brace was described by Nicholas (1983) as being designed to restrict anterior lateral instability. If there is an increase in translatory or rotatory motion causing the knee axis to shift into an unstable position the brace will act to restrain the shift. Anterior translation of the tibia is controlled in the Lennox-Hill brace by forces created by the pre-tibial bar, the derotation strap, the distal knee loop and the circumferential rubber band. A hyper-extension stop prevents movement into the unstable position of full extension. Rotatory instability is restrained by the contours and placement of the lateral leg pads, the medial knee disc, the circumferential rubber band above and below the knee and the de-rotation straps.

The Medicus brace consists of an extension stopper (10-15 degrees) to prevent full knee extension and a close-fitting tibial mold to control internal rotation of the tibia. A pressure system consisting of a femoral and tibial mold as well as four non-elastic straps help to control anterior translation of the tibia on the femur. The hinge joint provides further control of rotation and extension.

2.3.5 Brace Fit and Design

Walker et al., (1985) and Shafer et al., (1988) stated that one of the major problems with knee braces was that the joints of the brace follow kinematic pathways which are simpler than those of the natural knee joint. As a result the fixed hinges do not account for important axial rotaion and anterior-posterior translation. Thus, optimal stability is not achieved. Polycentric hinges more clearly simulate complex rolling and gliding of the knee during flexion and extension by providing a changing center of rotation. However, in order for the hinge to function properly it must be in line with the center of the joint line (Berretta et al., 1985). Thus any displacement of the hinge during dynamic activity renders the brace less effective.

Poor alignment between the orthosis and the natural knee joint motions may cause displacement of the brace during dynamic activity. Lew et al., (1982) stated that when an orthosis is applied to a joint conflict occurs as the orthosis attempts to force the knee to follow a simplified motion. Since this is impeded by joint structures, unwanted constraint forces develop in the suspension points of the orthosis causing the interface components to migrate over the limb segments. Some constraints are beneficial when they compensate for lacking stability but they can become detrimental if they disrupt the normal phases of knee motion. Also, displacement of the brace will interfere with its ability to control joint range of motion and thus make it less effective.

Not only is it important that the brace not be displaced in a vertical or horizontal direction but also that the brace conform to the specific anatomical contours of the knee joint. In a well fitted brace the tibial mold will be in close contact with the actual tibia in order to prevent translation and rotation and the brace hinges will align with the center of rotation of the knee joint.

2.4 Brace Studies

There have been many studies published involving the results of static and clinical testing of functional knee braces but there are only a few studies which employ dynamic testing. Although it is important that a brace functions in a static setting it does not necessarily imply that it is effective under dynamic conditions. Functional activities apply much greater stress on both the knee joint and the brace (Vardaxis, 1988). In dynamic activities components such as muscular force and joint compression loading act on the knee joint to stabilize it. A major criticism of both the clinical and in- vitro studies that have been published is their lack of generalizability to dynamic situations because the criterion variables used in a static situation do not measure efficacy in a dynamic situation. Therefore, it is important to first of all establish a method of testing functional braces during dynamic activity and secondly evaluate all braces both statically and dynamically.

2.4.1 Static Testing

Knutzen et al., (1984) and Hoffman et al., (1984) both demonstrated the ability of functional knee braces to control translation of the tibia on the femur under low stress loads. The forces used in these studies were of the magnitude of fifteen to twenty pounds of force which is substantially lower than the hundreds of pounds of force which are applied to the knee joint during dynamic activity (Marquette, 1988).

In a study by Coughlin et al., (1985) the A-C functional knee brace was tested under static conditions using the Genucom Knee Analysis system. The authors reported an average of 46 % decrease in internal rotation with the knee brace on. Measurements were taken while passive load was being applied to the joint.

In a study by Colville et al., (1986) the effectiveness of the Lennox-Hill brace in treating knee instability was both objectively and subjectively evaluated. The brace failed to significantly reduce maximal anterior subluxation of the tibia but did increase stiffness in the knee joint. Rotatory instability was improved an average of one grade on the measurement scale. Patients reported a significant decrease in episodes of "giving way" and athletic performance was improved by using the brace in 69 % of the patients. The subjective results for this study were obtained using a questionnaire while objective results for this study were evaluated by an apparatus that measured tibial subluxation. The authors concluded that a decrease in symptoms of instability when wearing the brace may be due to the ability of the brace to improve relative knee stiffness even though maximal laxity remained unchanged.

In a study by Bassett and Fleming, 1983 the efficacy of the Lennox-Hill brace in controlling anterior lateral rotatory instability of the knee was reported. A comparison was made of the degree of instability with and with out the brace applied during clinical tests. The results showed that 89 % of the knees with grade one instability and 45 % of those with grade two instability improved. However, this was static testing only. In the dynamic situation 70 % of the subjects complained of episodes of "giving way" while wearing the brace although this was not objectively measured. It is clear that there is need for further research to study the adaptation of the knee brace to functional activities in a controlled objective dynamic situation.

2.4.2 Dynamic Testing

A review of the literature presented few studies that address the topic of the analysis of knee braces during dynamic activity. Knutzen, Bates, Schot, & Hamill (1987) stated that the application of a knee orthosis significantly alters the kinematic characteristics of the knee joint. The influence of knee bracing was evaluated during the activity of running by examining ground reaction forces and knee joint parameters obtained using an electrogoniometer. Both knee brace conditions were shown to significantly reduce knee flexion during swing and support phases, as well as total rotation of the tibia on the femur and total varus/ valgus movement parameters of the experimental knee joint. The important question is whether this deviation helps to improve the stability of the knee or whether it hinders joint function stability.

Shiavi, Limbird, Frazer, Stivers, Strauss, & Abramovitz (1986) undertook a study designed to establish the dynamic kinematics of ACL deficient knees during walking at different speeds and during a pivoting movement. He found that there was a significant tendency towards adduction and external rotation during certain periods of the stride. If these kinematics represent an attempt by the subject to stabilize the ACL deficient braced knee then perhaps the orthosis should also reflect the same limitations and kinematics. That is, by limiting internal rotation, the brace can improve knee stability.

In a study by Knutzen, Bates and Hamill (1983), an electrogoniometer was used to measure dynamic range of motion of the affected or damaged knee while using a support knee brace and a functional derotation brace (Lennox-Hill). The results showed a general reduction in knee flexion during swing and support phase when the derotation brace was applied. The Lennox-Hill brace also limited both internal and external rotation when compared with the no brace condition and the contralateral intact limb. The amounts of restriction during knee extension was not studied.

Knutzen et al., (1984) studied the influence of support braces and derotation braces on tibial rotation in post surgical knees. The results suggested that the knee orthosis tested showed a trend towards limiting external rotation more than internal rotation. However, this study was completed in a static setting with the hip and knee at 90 degrees of flexion and thus the results though important can not be generalized to include dynamic activities. Although both of Knutzen's studies show a trend toward limiting external rotation it must be remembered that these studies were done on post-surgical ACL deficient knees.

Van Horn , MacKinnon, Witt, & Hooker (1988) presented a study concerning the kinematic analysis of gait patterns among subjects wearing the Anderson Knee Stabilizer brace, McDavid Knee Guards and no brace. Although the braces tested are prophylactic and not functional orthoses the results are worth mentioning. Fourteen gait variables were measured for each brace and speed condition. There was an increase in hip and knee flexion and knee angular velocity with and without braces at 8 mph as compared to 4 mph, a decrease in knee extension when either brace was worn and a minimal gait pattern difference with the Anderson Knee Stabilizer as compared with the McDavid Knee Guard. The results of this study demonstrated that no clear superiority exists between the braces' effect on gait characteristics measured. The authors suggest that other parameters should be considered when evaluating braces. In this present study the intention was to evaluate restrictions on knee extension during dynamic activities.

Inoue, McGunk-Burleson, Hollis, & Woo (1987) demonstrated that restriction to the joint motion can have a significant influence on which ligaments are being put under stress. The results of his study showed that when knee motion is limited to varus-valgus rotation the medial collateral ligament is the primary restraint to valgus stress but when tibial rotation and translation are allowed the medial collateral ligament has less effect on valgus stability and the ACL becomes more of a stabilizing factor in the knee. It is thus possible that by limiting the tibial rotation and anterior translation in the knee joint by using an orthosis, the ACL deficient knee can be better stabilized by the medial collateral ligament playing a greater role. This would reduce the function of the ACL resulting in less stress being placed on the already damaged ligament.

2.4.3 Brace Fit Tests

In a dynamic situation the forces being transmitted through the knee joint prevent the orthosis from providing subtle control of anterior translation of the tibia on the femur (Beck et al., 1986; Bassett & Fleming, 1983). Therefore, control of the range of motion of the knee must occur if the orthosis is to provide joint stability. The orthosis must be anchored to the soft tissue adequately so that the limitations imposed on the dynamics of the brace as designed by the manufacturers (eg. extension stopper) can be transmitted to the skeletal system resulting in control of the femur and tibia interaction.

Functional instability in an ACL deficient knee usually manifests itself as lateral tibial plateau rotatory translation produced by the movements of extension and internal rotation (Lipke et al., 1981). Therefore a knee orthosis must limit extension and internal rotation of the tibia on the femur if it is going to provide stability to the damaged knee. Certain factors will influence the effectiveness of controlling knee joint range of motion. One such factor is the amount of movement which occurs between the brace and the knee joint. If the brace is not secure it will migrate during dynamic movement. This will result in a change in position of the various components of the brace which are necessary for the overall effective function of the brace. This shift may impede the mechanics of these components making the brace less effective. For example, the purpose of the tibial mold is to control tibial rotation. The mold is effective because of its close fit to the tibia and because it restricts rotation at the proximal end of the tibia where the movement originates. If the tibial mold migrated distally it would not function at an optimum level. Displacement of the brace may also change the position of the popliteal strap making it a less effective restrictor of knee extension. Lew et al., (1982) developed a method to quantitatively measure the relative efficiency of knee orthoses by comparing migration during motion. The pistoning tendency was quantified by using a transducer which measured the portion of the orthotic constraint force which was directed parallel to the side bars which attached the joints to the orthotic interface components. The results showed that there was no significant difference in migration for different types of knee orthoses but there was a difference between the types of activity. The study did not establish what influence the migration of the brace had on joint kinematics.

Van Horne et al., (1988) stated that they found no displacement of the brace in relation to the knee joint during the activity of running . This may explain why most subjects when completing scoring scales for functional activity levels state that they have little difficulty during straight running activities (Kettlekamp & Thompson, 1975; Lysolm & Gillquist, 1982). However, many athletes complain of instability with the brace during high force, high impact pivoting movements. The proposed study will use brace fit and brace displacement as criterion variables for comparing brace efficacy of the three braces being studied.

2.4.4 Summary

The literature supports the concept that functional knee braces are in part designed to protect the knee joint and provide increased stability by controlling the range of motion of the knee joint. Specifically, by limiting internal rotation and knee extension the functional instability seen in ACL deficient knees (ie. 'giving way') can be controlled. Thus, control of internal rotation and extension are used as criterion variables in this study to evaluate the efficacy of functional knee braces.

Previous research indicates that the effectiveness of the knee orthosis is also determined by the fit of the brace. A brace that does not fit properly is unable to effectively control knee joint range of motion and as a result the stability and mechanics of the joint are compromised. In this study brace fit was evaluated by the criterion variables of approximation of the tibial mold and total displacement of the brace after running.

Chapter 3

METHODOLOGY

3.1 Introduction

In light of the literature review it is clear that control of knee joint range of motion by the knee orthosis is a very important factor for evaluating the efficacy of knee braces in stabilizing the knee joint during dynamic activity.

There are several factors which may affect the ability of the knee orthosis to control knee joint motion. These include improper fit of the orthosis as displayed by horizontal and vertical displacement of the brace in relation to the knee joint and excess movement of the brace on the tibia and femur due to compression and wobbling of soft tissue. In this study the first two factors were evaluated. As described in section 2.3.5, as an external support the function of a knee brace is impaired if the brace does not fit properly. Displacement of the brace, in either a horizontal or vertical direction changes the alignment of the components of the brace with the knee joint and thus may diminish the efficacy of that brace. For example brace migration changes the position of the tibial mold and popliteal strap rendering them less effective in performing their functions as restrictors of joint range of motion.

Three separate dynamic tasks were chosen as a means of determining the functional characteristics of the three braces being evaluated. From the results of these tests the efficacy of the braces during dynamic activity were determined.

The first task involved measuring the active range of motion (flexion, extension, internal rotation and external rotation) of the ACL deficient knee and the braced ACL deficient knee. The purpose of this test was to determine whether the functional knee brace controls internal rotation and extension, two movements which can cause increased instability in the knee joint during dynamic activity (Noyes et al., 1984, Lipke et al.,1981). Although this test does not excessively load the knee it does give a clear indication of the restrictions which the brace applies to the joint.

In order to simulate a more dynamic task, subjects were instructed to perform an instep straight soccer kick representing a high velocity, high force activity. The purpose of the test was to determine how effective the brace was in limiting knee extension. This was determined by measuring the brace angle at the end of the kick just before the knee started to flex and comparing this to the joint angle at the same point in time (brace/knee joint congruency). It is important to the stability of the knee joint that the knee is limited from extending completely, otherwise, the joint becomes malaligned (pivot shift) and upon landing on the kicking leg there would be a greater tendency for the knee to collapse since the force could not be properly transmitted from the tibia to the femur (Marquette, 1988).

The final dynamic task consisted of having the subjects jog at 4-6 MPH on a treadmill for ten minutes. The purpose of this task was to determine brace fit in terms of the amount of displacement occurring in the brace during dynamic activity. Since most functional tasks involve some degree of running this test was a good indicator of possible brace migration during a running activity. As was previously discussed, a brace can function effectively only if its components are held in position so that they can affect the appropriate anatomical areas of the knee joint (Lew et al., 1982).

A further test to determine brace fit consisted of measuring the distance of the tibial mold to the tibia during various points of knee flexion. This test however, could only be applied to two of the braces since the third brace, the Lennox-Hill does not have a tibial mold. A close fitting mold is effective in controlling tibial rotations.

3.2 Subjects

The subject population for this study consisted of eighteen individuals with a unilateral chronic isolated ACL deficient knee as diagnosed clinically via arthroscopic surgery. Subjects were excluded if they had one of the following conditions: meniscal injury, medial collateral ligament injury, lateral collateral ligament injury or ACL reconstructive surgery. Subjects were between the ages of eighteen and thirty-five in order to avoid complications due to possible arthritic conditions which may be found in an older age group. Fifteen of the subjects had one of the previously described functional knee braces prescribed in order to improve knee stability. In addition, a group of three subjects were fitted for all three braces and each subject evaluated with each brace.

3.3 Subject Preparation

Each subject was required to wear shorts, a t-shirt and running shoes during the experimental session to allow easy viewing of the anthropometric landmarks. In order to aid in the collection of kinematic data from the film the following reference points of the ACL deficient knee were marked with fluorescent tape; the greater trochanter, the lateral joint line of the knee and the lateral malleolus (figure 3.1). Markers were also placed on the orthosis at the following points: the superior lateral border, the lateral hinge and the lateral inferior border (figure 3.2).

3.4 Testing Apparatus - Cinematography

The data for this study was collected using a high speed camera set at a frequency of 30 Hz. The location of the camera depended on two factors: the plane of action and the area of the subject which was to be viewed. In order to be able to digitize the movement, the filming was done at a perpendicular angle to the plane of movement. For all the testing procedures in this study the filming was done from a side view. Once the film was processed it was displayed frame by frame on a video digitizer so that the appropriate relative angles could be determined.

Given the co-ordinated data from the anatomical landmarks at either end of a limb segment the absolute segment and joint angles were determined. In this study the relative angle of the knee joint equaled the absolute angle of the shank minus the absolute angle of the thigh. The relative angle of the brace was calculated by subtracting the absolute angle of the proximal brace segment from the absolute angle of the distal segment.

3.5 Description of the Study

The purpose of this study was to design a quantitative method of evaluating the efficacy of functional knee braces during active and dynamic activity. As previously mentioned, it was established that brace efficacy can be measured by control of joint range of motion and brace migration. Two movements, which, when limited, help control joint instability are, knee extension and internal rotation. By limiting these movements the brace prevents the pivot shift phenomenon or joint malalignment from occurring and thus improves stability and protects the joint from possible re-injury. It is through the actual design of the brace that the limitation or control of joint movement is achieved. A poor fitting brace or a brace that becomes displaced during activity can not provide adequate support or protection. Lew et al., (1982) alluded to the fact that in order for a knee orthosis to be effective it must " act as one" with the knee joint.

The criterion variables that were used in this study to evaluate the efficacy of a knee orthosis were determined in the previous two chapters. The following discussion will explain how these variables were measured.

3.5.1 Task One - Active Range of Motion

a) Subjects were asked to actively flex and extend, as far as possible, their ACL deficient knee with and without the knee brace.

b) Angle measurements were obtained using a standard goniometer where the proximal arm was aligned with the greater trochanter, the distal arm with the lateral malleolus and the center axis with the center of the lateral joint line of the knee.

c) Subjects were then seated in a chair, with the hips and knees at 90 degrees and each foot was placed on a rotating platform one at a time. The neutral zone was established by placing the foot in a position which was parallel to the coronal plane of the body (Osternig, Bates, & James, 1980). Subjects were then asked to first internally and then externally rotate the tibia on the femur as far as possible. Angles of rotation were measured by a goniometer resting on the rotating platform.

3.5.2 Task Two - The Efficacy of the Knee Brace in Controlling Knee Extension During a High Velocity, Functional Task.

a) Subjects were asked to perform a straight toe instep soccer kick. This action was repeated three times.

b) The high speed video camera was placed so that it was perpendicular to the saggital plane. The distance from the camera to the kicking leg was recorded. The movement from contact to follow through was filmed.

c) The relative knee angle and the relative brace angle at the end point of follow through was calculated from the data. This point was defined as the frame just prior to the point where the knee begins to descend and flex. The ability of the knee brace to limit full knee extension and thus prevent ' knee kickback' from occurring during high acceleration activities such as kicking is important because it aids in avoiding the possibility of greater instability upon landing, due to malalignment of the knee joint as a result of being forced into the last degree of extension. This test evaluates the restraining characteristic for knee extension of the brace under high load activity without placing the subject at risk of possible re-injury.

3.5.3 Task Three - Brace Fit

Lew et al., (1982) suggested that displacement of the knee brace during dynamic activity could disrupt the normal phases of knee motion and could impede the actual function of the knee brace which is to stabilize the knee joint.

Malalignment of the brace with the knee joint can affect the efficacy of the orthosis (Walker et al., 1985; Shafer et al.,1988).

Therefore, this testing procedure was specifically designed to measure the amount of vertical and horizontal displacement of the brace during strenuous repetitive dynamic activity.

a) Subjects were asked to jog at 4-6 MPH for ten minutes.

b) The total displacement of the brace in relation to the knee joint was calculated by measuring the position of the center of the lateral hinge in relation to the center of the lateral knee joint line with the knee flexed at 15 and 90 degrees both before and after running. If the lateral plateau was not visible another origin such as the inferior pole of the patella was used.

c) As a further investigation of brace fit subjects placed their ACL deficient braced knee at angles of 15, 30, 60, and 90 degrees of knee flexion (as measured by a goniometer). The distance from the knee to the tibial mold was measured. The following three measurements were taken:

1. center of the medial lip of the brace to the center of the medial tibial plateau

2. center of the central lip of the brace to the center of the patellar tendon

3. center of the lateral lip of the brace to the center of the lateral tibial plateau (figure 3.3).

3.6 Experimental Design

Task one: Active range of motion (ACL deficient knee - braced ACL deficient knee) (Degrees)

	Brace 1	Brace 2	Brace 3
Extension			
Internal rotation			

This is a completely randomized design with one independent variable with three levels.

Criterion Variables:

1) extension control (degrees) = extension of ACL deficient - extension of braced ACL deficient

2) internal rotation control (degrees) = internal rotation of ACL deficient - internal rotation of braced ACL Deficient.

Task two: Kicking task (relative brace angle - relative knee angle)

	Brace 1	Brace 2	Brace 3
Brace/Joint Congruency			

This is a completely randomized design with one independent variable (braces) with three levels.

Criterion Variable:

Brace / joint congruency (mm) = relative brace angle - relative knee angle.

Task Three: Brace Fit

	Brace 1	Brace 2	Brace 3
Brace fit A and B			

A) Flexion Angle (Degrees)	Distance From Center of Lateral Lip to Center of Lateral Tibial Plateau	Distance From Center of Central Lip to Patellar Tendon	Distance From Center of Medial Lip to Center of Medial Tibial Plateau
15			
30			
60			
90			

B) Position of the Lateral Hinge Center Before Runing - Position of the Lateral Hinge Center After Running= Total Brace Displacement During Running

Experiment two of this study involved the subjects tested for all three braces, and uses the same experimental design as in part one (described above) except that it was a randomized block design with repeated measures with each subject acting as a block.

Figure 3.1: Anthropometric Landmarks for an ACL Deficient Knee

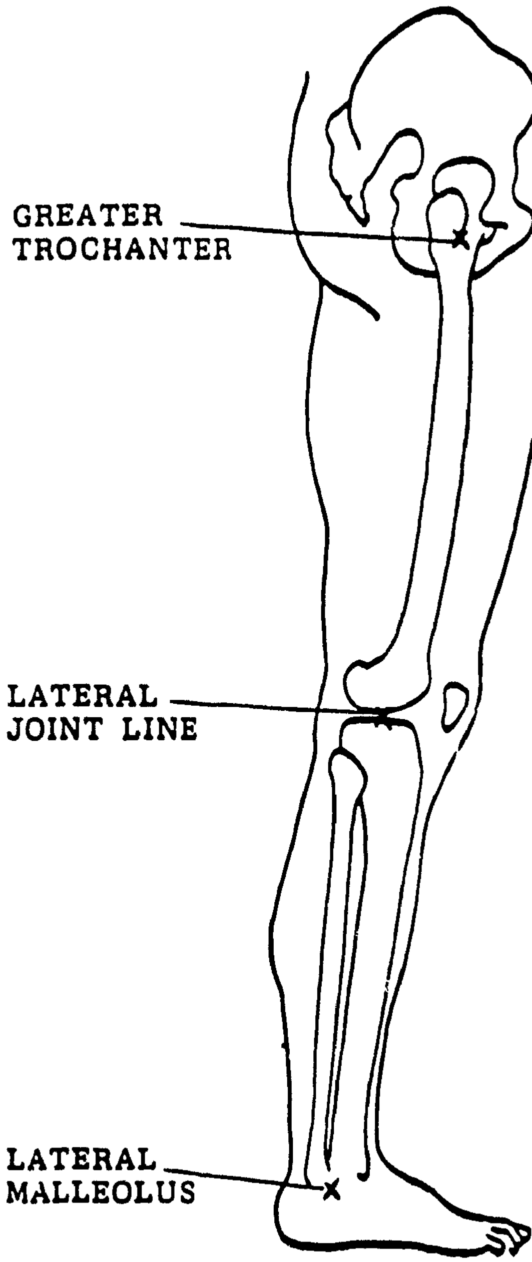


Figure 3.2: Brace Landmarks Used to Measure Congruency and Migration

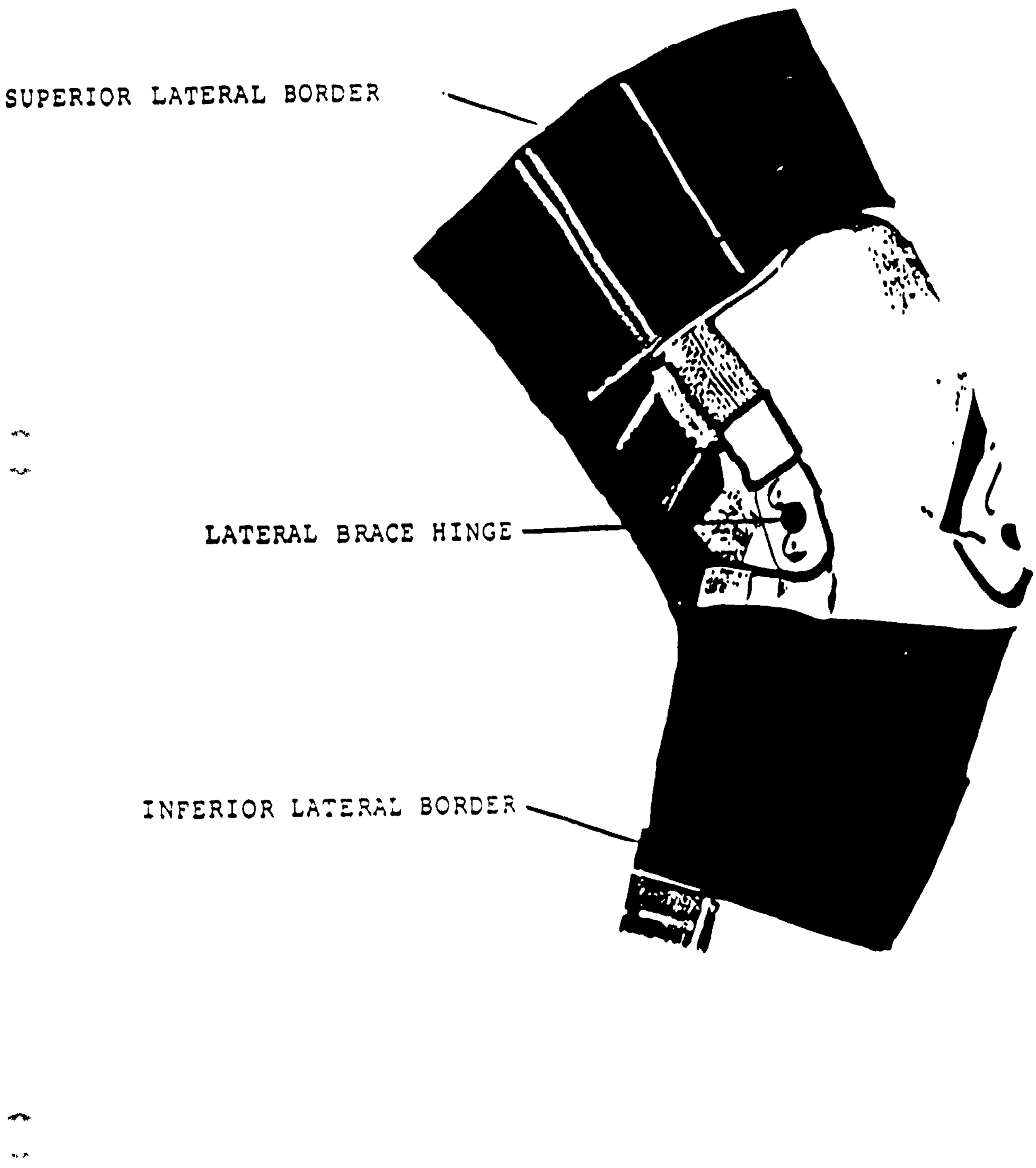
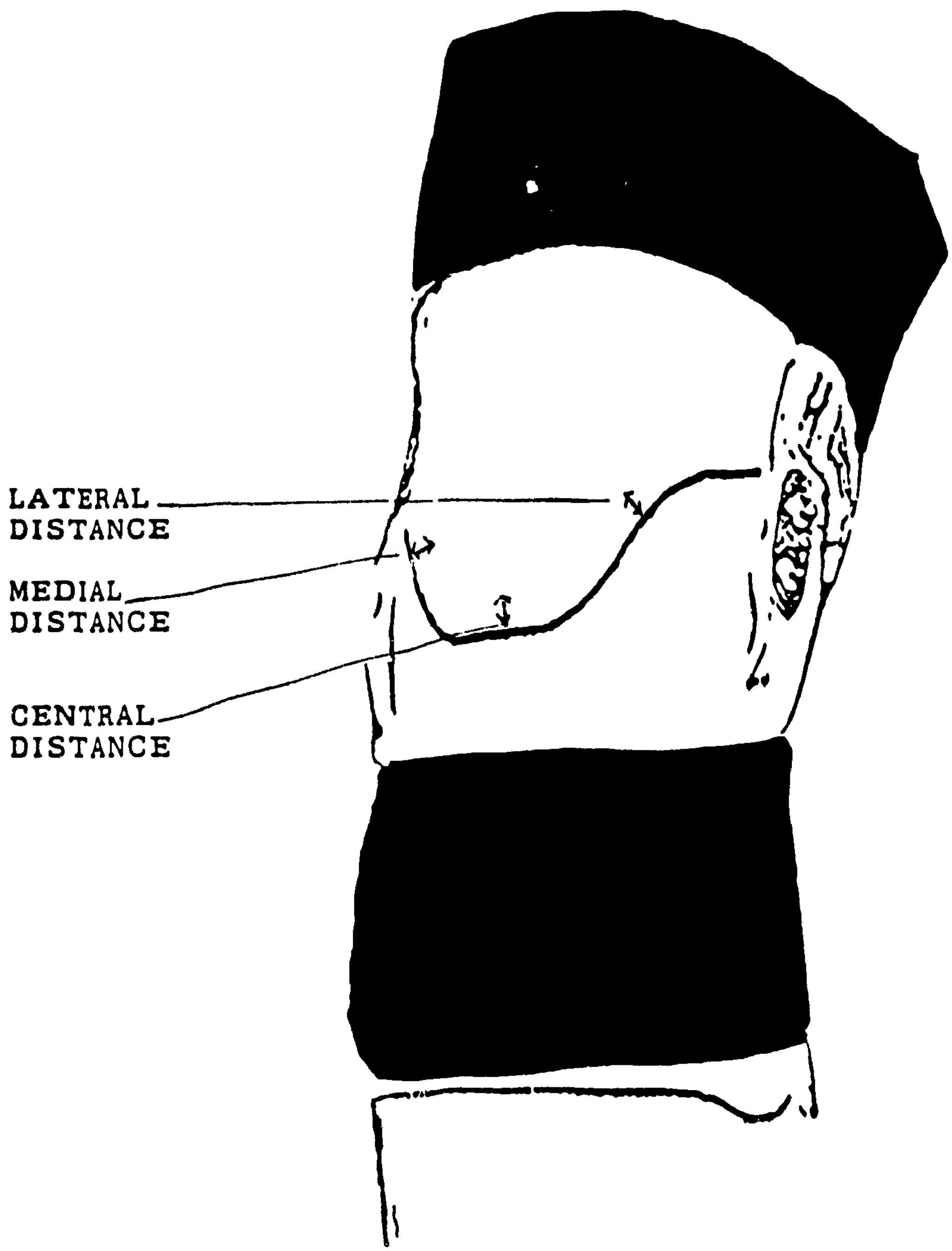


Figure 3.3: Congruency of Tibial Mold with Tibia



Chapter 4

RESULTS

4.1 Introduction

The purpose of this study was to evaluate and compare the efficacy of three commercial functional knee braces based on the following criterion variables:

1) range of motion of the deficient knee - range of motion of the braced deficient knee.

2) relative brace angle - relative knee angle (brace / knee joint congruency).

3) total displacement of the brace during a running task.

4) approximation of the tibial mold.

Variables one and two reflect the ability of the knee brace to control range of motion, particularly, movements such as internal rotation and extension which render the knee joint unstable. Variables three and four were used to determine the general fit of the brace or how well the brace design approximated the contours of the knee joint. This factor was deemed extremely important since the beneficial restrictions imposed by the brace in order to stabilize the knee joint could only be transmitted to the skeletal system if the brace was well aligned with the knee joint (Lew et al., 1982).

The subject sample consisted of three groups of eight subjects each. Subjects were designated to the groups according to which of the three knee orthoses they had been prescribed. A second subject sample consisted of three of the subjects who had been prescribed all three knee braces.

4.2 Analysis of Control of Active Range of Motion : Experiment I

The results for the control of range of motion are indicated in tables 4.1 - 4.4 and figures 4.1 and 4.2. Table 4.1 demonstrates the ability of the knee brace to control or limit knee extension and internal rotation during active movement. The results in table 4.1 indicate that Brace 2 had the most effective device for controlling internal rotation of the tibia on the femur followed by Brace 3 and finally Brace 1. In addition, the results in table 4.1 also demonstrate that brace 3 was the most effective controller of knee extension followed by Brace 2 and then Brace 1.

Table 4.1: Control of Joint Range of Motion (deficient knee - braced deficient knee) (degrees)

(mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Internal rotation	-1.18 (7.6)	4.44 (4.1)	2.38 (2.6)
Extension	6.00 (6.1)	10.50(2.7)	13.12(4.6)

The results from table 4.1 were further statistically analyzed using a one-way Anova. This data is presented in tables 4.2 and 4.3. The statistical analysis for knee extension revealed significant differences between the three Brace groups at the $p<.05$ level (table 4.2). The statistical analysis for knee internal rotation shows that no two groups were significantly different and therefore the null hypothesis was accepted (table 4.3)

Table 4.2: Anova Table of Knee Extension

source	d.f.	sum of squares	mean squares	f prob.
Between Groups	2	207.60	103.80	.02
Within Groups	21	460.64	21.94	
Total	23	668.23		

$p < .05$

There are significant differences between the groups at the $p < .05$ level.

Table 4.3: Anova Table for Internal Rotation

source	d.f.	sum of squares	mean squares	f prob.
Between Groups	2	129.56	64.78	.12
Within Groups	21	569.56	27.12	
Total	23	699.13		

$p < .05$

No two groups are significantly different.
Therefore, H_o: $u_1 = u_2 = u_3$ is accepted.

The results in table 4.2 were further analyzed in order to determine which groups were significantly different. A post-hoc Tukey test was used and the results are indicated in table 4.4. It was determined that Brace 1 and Brace 3 were significantly different at the $p<.05$ level for effective control of knee extension during active movement.

Table 4.4: Tukey Test Results for Knee Extension

	Brace 1	Brace 2	Brace 3
Brace 1			
Brace 2			
Brace 3	*		

$p < .05$

Figures 4.1 and 4.2 provide a graphic demonstration of the efficacy of each knee brace in controlling knee internal rotation and extension during active range of motion.

4.3 Analysis of Brace/Knee Joint Congruency During Dynamic Kicking Task : Experiment I

The results of brace/knee joint congruency during a dynamic kicking task are presented in table 4.5. The results indicate that Brace 3 was the most effective of the three braces in controlling knee extension during a forceful kicking movement. Brace 2 proved to be the least effective resulting in poor brace/knee joint congruency.

Table 4.5: Brace/Knee Joint Congruency During Dynamic Kicking Task (brace angle - knee joint angle) (degrees)

(mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Brace/knee joint congruency	5.38 (3.3)	6.13 (2.1)	1.87 (2.17)

Figure 4.1: Internal Rotation of the ACL Damaged Knee - Braced ACL Damaged Knee : Experiment I

(Degrees)
Vs
Brace Type

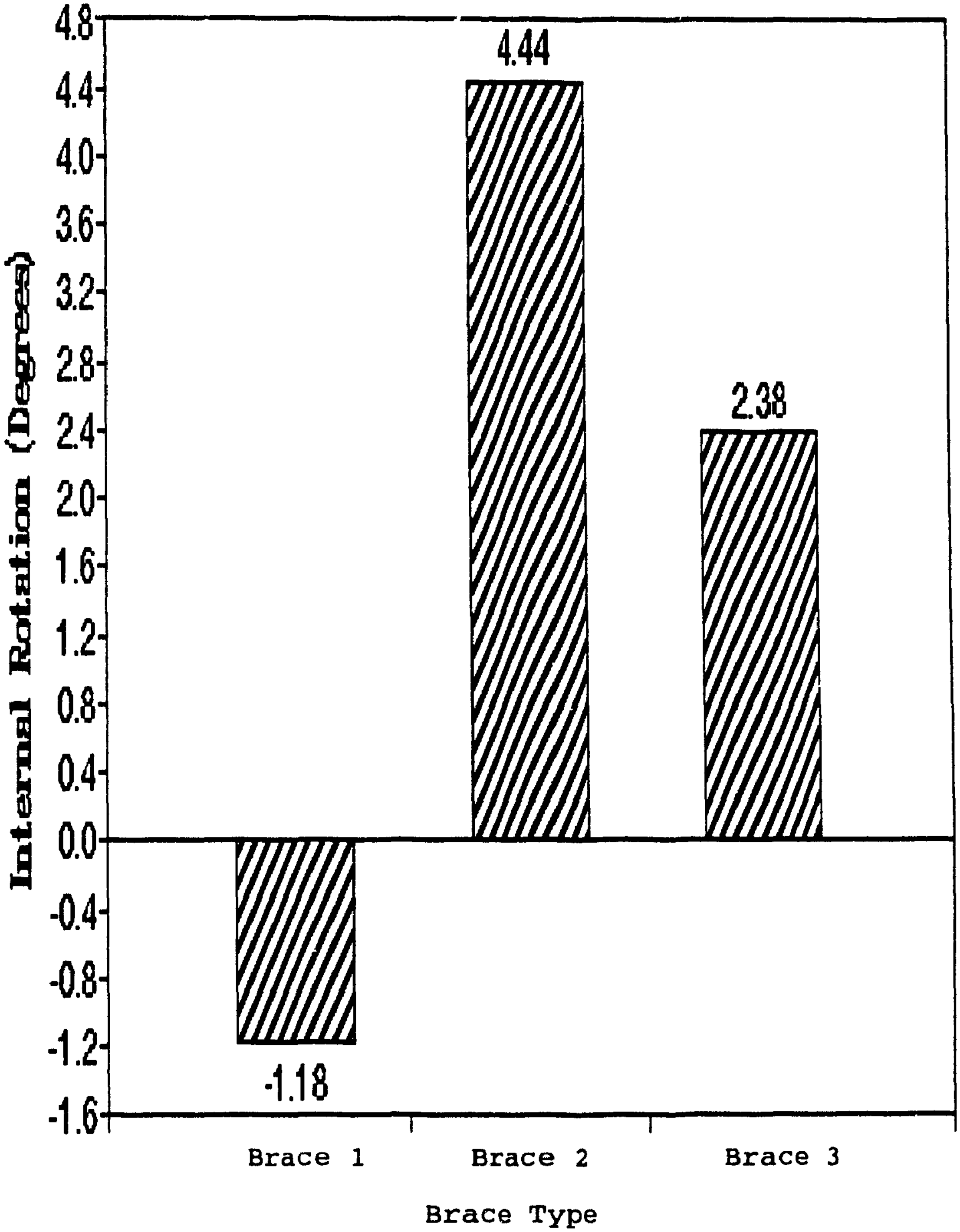
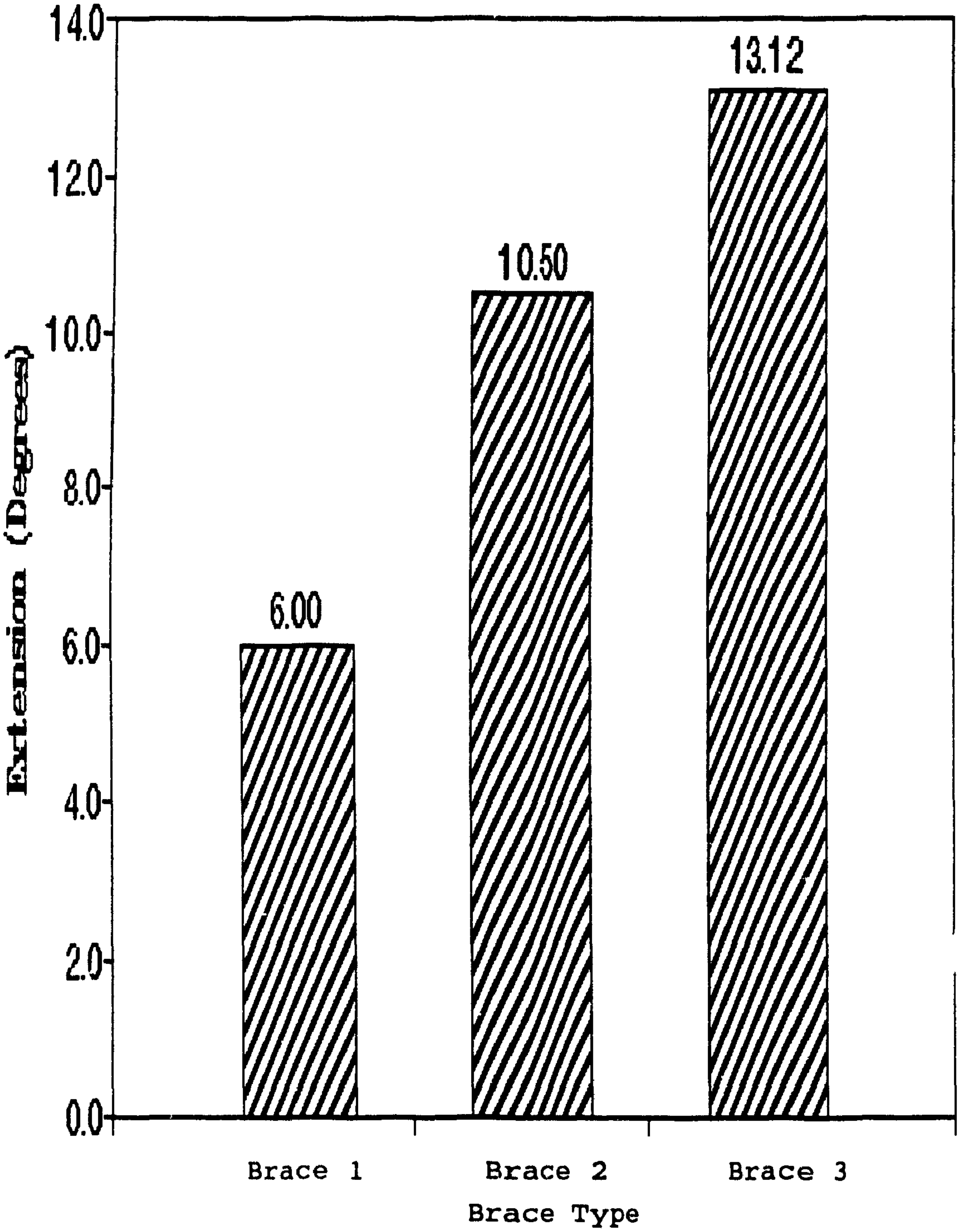


Figure 4.2: Extension of the ACL Damaged Knee - Braced ACL Damaged Knee : Experiment I

(Degrees)
Vs
Brace Type



* Results for Brace 3 & Brace 1 are significantly different at the $p < .05$ level.

The results in table 4.5 were further statistically analyzed by performing a one-way Anova. These results are presented in table 4.6. The statistical analysis for Brace/knee joint congruency indicates that there were statistically significant differences between the three knee brace groups.

Table 4.6: Anova Table for Brace/ Knee Joint Congruency

source	d.f.	sum of squares	mean squares	f prob.
Between Groups	2	82.33	41.17	.008
Within Groups	21	141.63	6.74	
Total	23	223.96		$p < .05$

The results in table 4.6 were further analyzed in order to determine which groups were significantly different. A post hoc Tukey test was used and the results are presented in table 4.7. It was determined that Brace 3 and Brace 1 were significantly different at the $p<.05$ level as well as Brace 3 and Brace 2. A graphic demonstration of this data is presented in figure 4.3.

Table 4.7: Tukey Test Results for Brace/ Knee Joint Congruency

	Brace 1	Brace 2	Brace 3	
Brace 1			*	
Brace 2			*	$p < .05$
Brace 3				

4.4 Analysis of Brace fit : Experiment I

The final criterion variable used to evaluate the efficacy of the three orthoses consisted of brace fit. This was measured first by the displacement of the hinge of the brace during a ten minute running task and secondly by the approximation of the tibial mold to the tibia. The results of the displacement values are listed in tables 4.8 - 4.10 and figure 4.4.

Figure 4.3: Braced Angle - Knee Angle During Kicking Task : Experiment I

(Degrees)
Vs
Brace Type

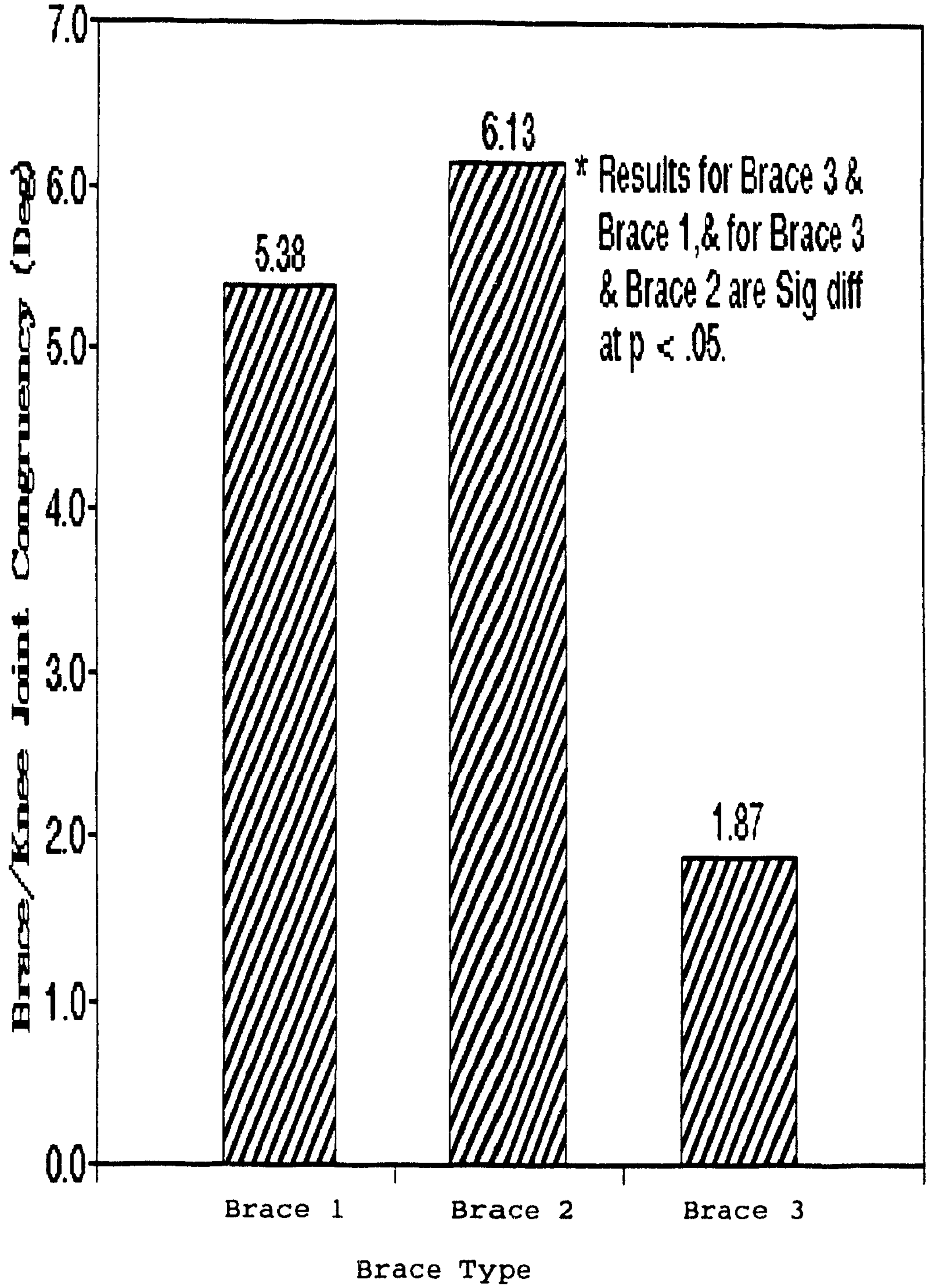


Table 4.8 demonstrates the ability of the knee brace to maintain its postition during a dynamic running task. The results indicate that Brace 3 migrated the least during the test followed by Brace 2 and then Brace 1.

Table 4.8: Total Displacement of the Brace During the Running Task (cm.)

(mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Total Displacement	1.69 (1.5)	0.84 (.72)	0.06 (.12)

A one-way Anova was then performed on the data from table 4.8 and the results indicated that the three brace groups were significantly different in the amount of displacement that occured during the running task (table 4.9).

Table 4.9: Anova Table for Total Displacement of the Brace : Running Task

source	d.f.	sum of squares	mean squares	f prob.
Between Groups	2	10.57	5.29	.01
Within Groups	21	20.15	0.95	
Total	23	30.72		

$p < .05$

There was a significant differences between the groups. Therefore Ho: U1=U2=U3 is rejected.

The results from table 4.9 were further analyzed (post hoc Tukey) and it was determined that statistically significant differences occured between Brace 1 and Brace 3 displacement results. This information is presented in table 4.10. A graphic representation of these results is found in figure 4.4.

Table 4.10: Tukey Test Results for Total Displacement of the Brace: Running Task

	Brace 1	Brace 2	Brace 3
Brace 1			
Brace 2			
Brace 3	*		

$p < .05$

The second criteria used for measuring brace fit consisted of evaluating the approximation of the tibial mold to the tibia before and after running. Measurements were taken for Brace 2 and Brace 3 only, since Brace 1 did not have a tibial mold as part of its design. For both groups there was no change in the approximation values before and after running. Both braces demonstrated good approximation of the tibial mold (0 mm distance) in knee extension with gradual gapping (1.5 mm) as the knee was flexed to 90 degrees. Although this is not an integral part of the present study, it is believed that the tibial mold plays an important role in the control of the anterior translation of the tibia on the femur particularly in extension and under low loads (Berretta, 1985; Hunter, 1985). Taking this into consideration it can be stated that a close fitting tibial mold should improve the efficacy of a knee brace.

4.5 Analysis of Control of Active Range of Motion : Experiment II

The second part of this study consisted of three subjects each of whom had been prescribed all three functional knee braces. The criterion variables used in experiment one of this study to determine the efficacy of the knee orthoses were also used in part 2 of this study. The results demonstrating control of range of motion are presented in table 4.11.

Table 4.11: Control of Range of Motion (deficient knee - braced deficient knee) (degrees)
(mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Internal rotation	4.3 (0.6)	7.7 (6.6)	4.0 (2.0)
Extension	4.0 (0.0)	7.7 (1.5)	9.3 (3.1)

The results in table 4.11 indicate that Brace 3 was the most effective in controlling knee extension during active knee movement and that Brace 2 was the most effective in controlling internal rotation. Brace 1 was the least effective in controlling both variables. These results show similar trends as the results demonstrated in experiment one of this study. However, because of the smaller sample size these results when analyzed using a one-way Anova showed no significant diferences. A graphic presentation of this data is found in figures 4.5 and 4.6.

4.6 Analysis Of Brace/ Knee Joint Congruency During Dynamic Kicking Task : Experiment II

The second criterion variable evaluated was the brace/ knee joint congruency during the kicking task as measured by the difference in the relative angle of the brace and the relative angle of the knee joint at the end of the knee extension phase of the kick. The results of this task are presented in table 4.12. Once again further analysis (Anova) showed no significant differences.

Table 4.12: Brace/ Knee Joint Congruency During Dynamic Kicking Task (brace angle - knee joint angle) (degrees) (mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Brace/ knee joint congruency	8.3 (1.5)	6.3 (2.3)	1.0 (0.0)

A graphic presentation of Brace/ knee joint congruency results are depicted in figure 4.7.

Figure 4.4: Total Displacement During Running Task (cm) vs Brace Type : Experiment I

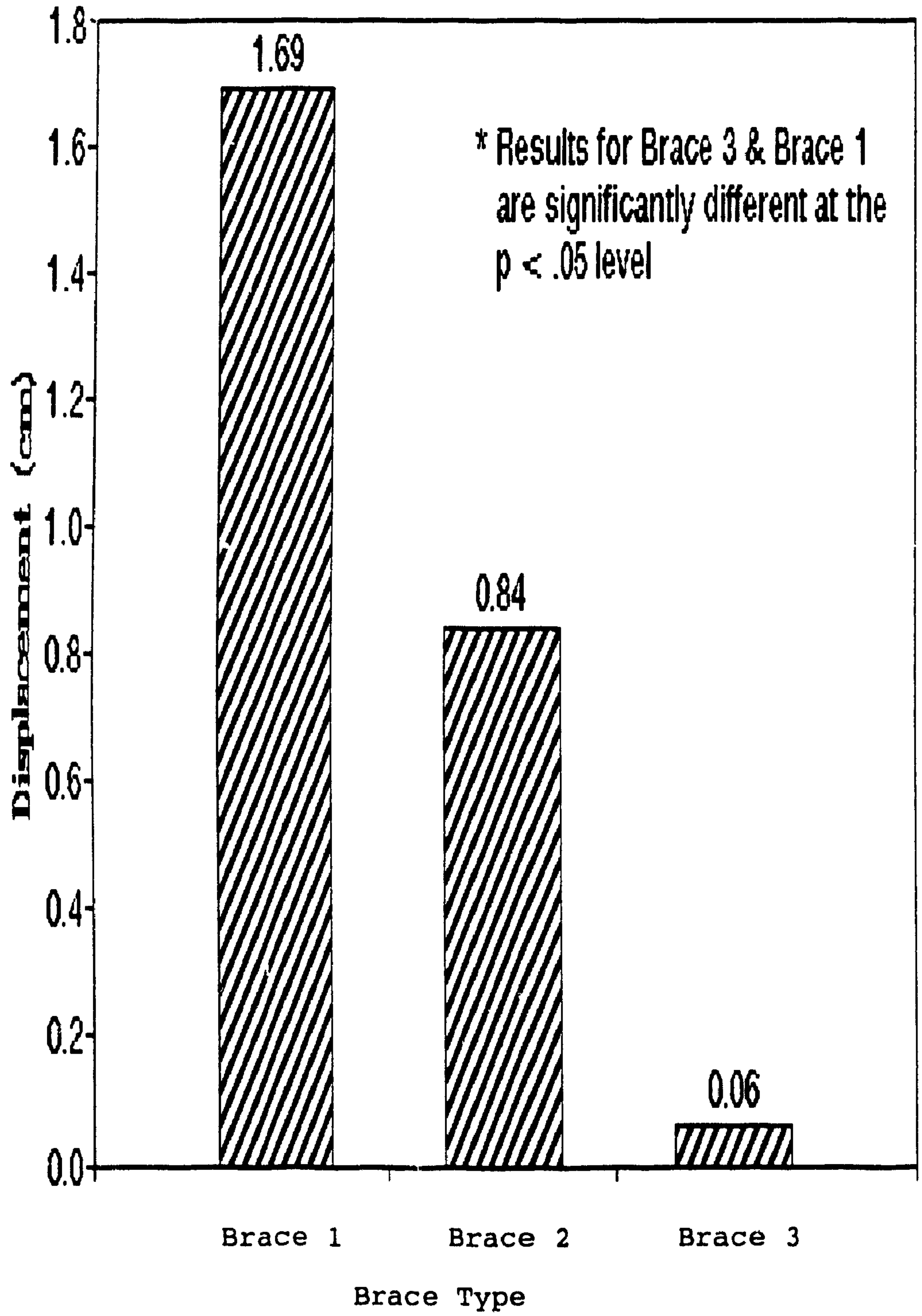


Figure 4.5: Internal Rotation ACL Damaged Knee - Braced ACL Damaged Knee : Experiment II

(Degrees)
Vs.
Brace Type

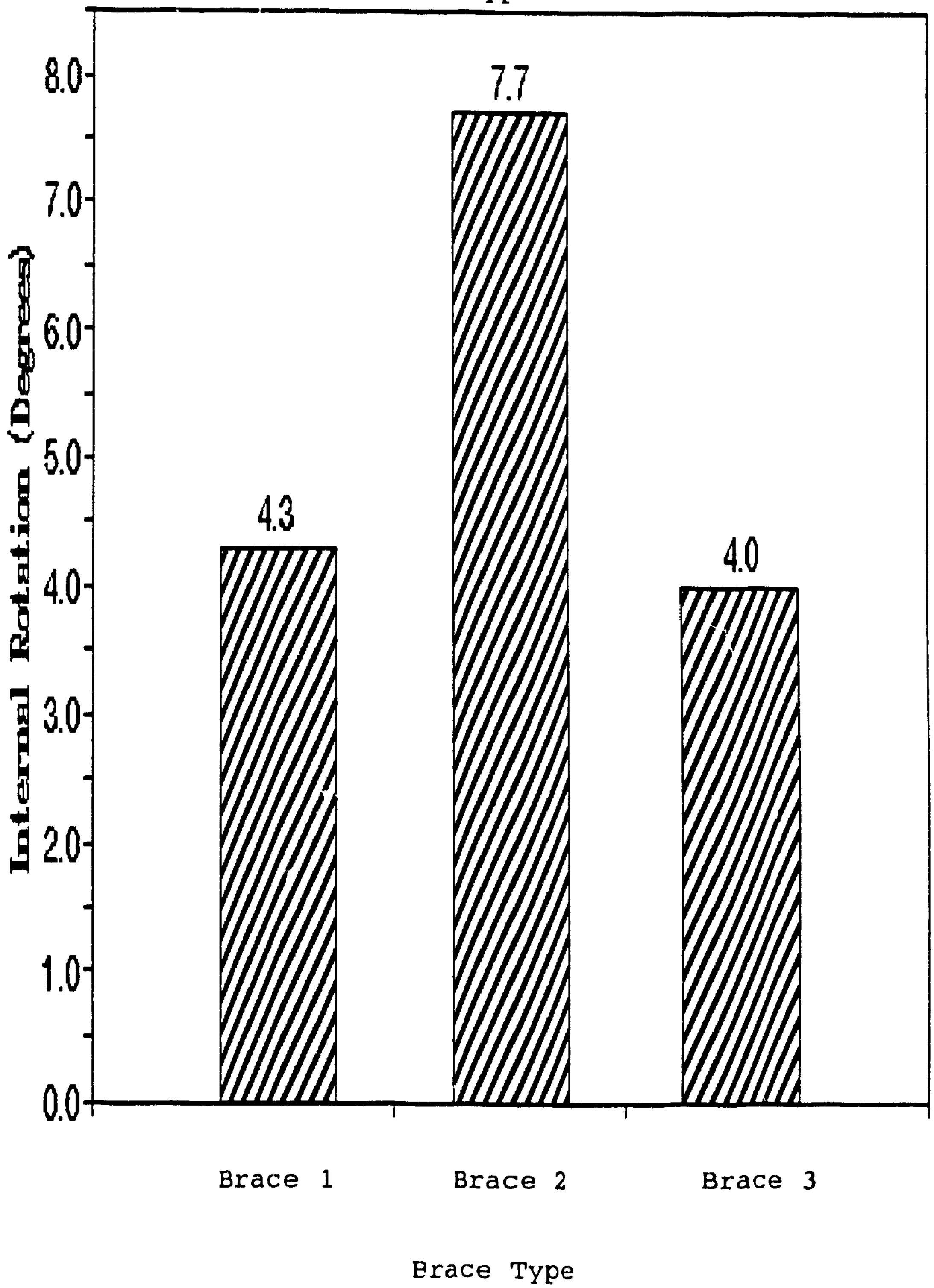


Figure 4.6: Extension of ACL Damaged Knee - Braced ACL Damaged Knee : Experiment II

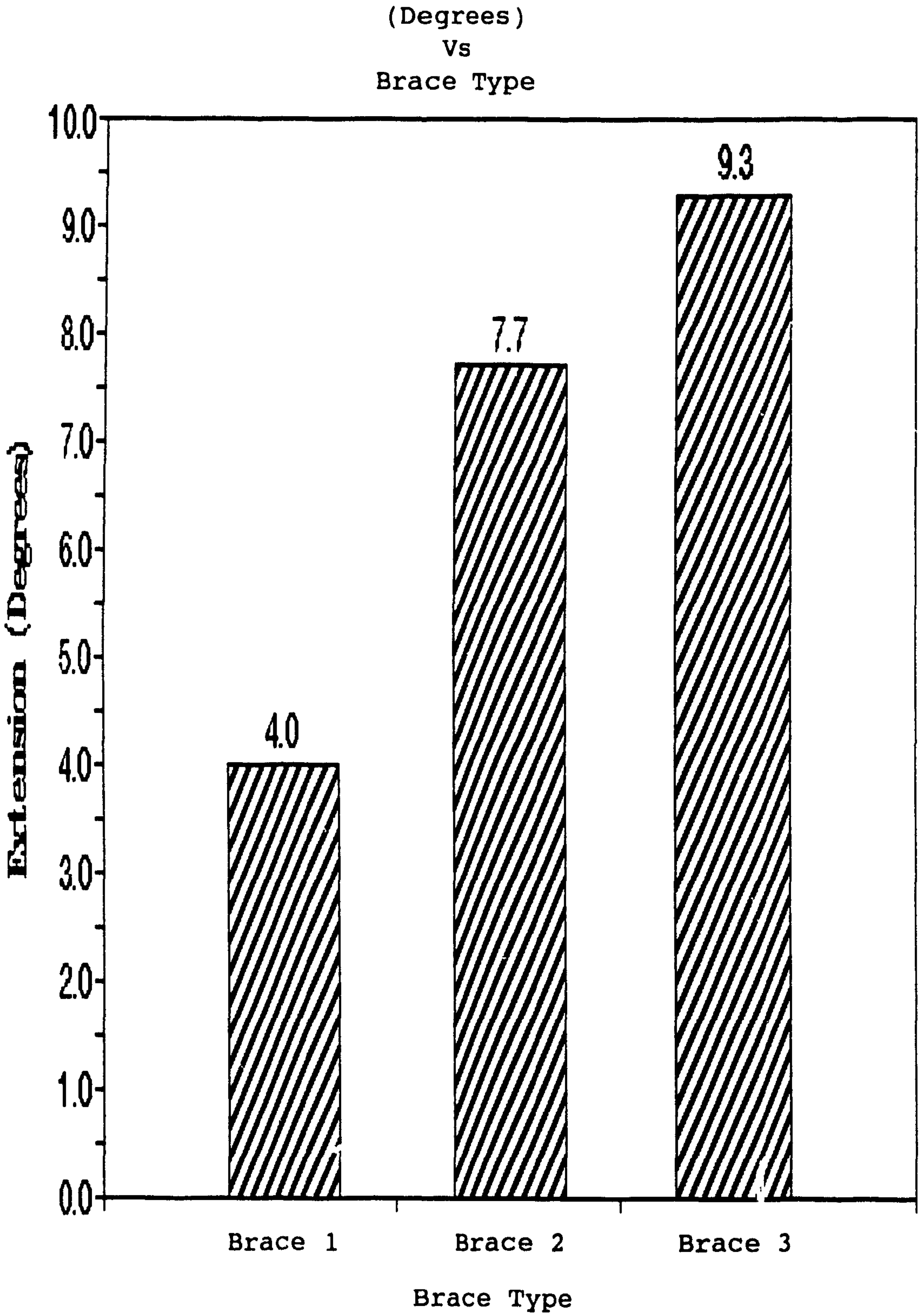
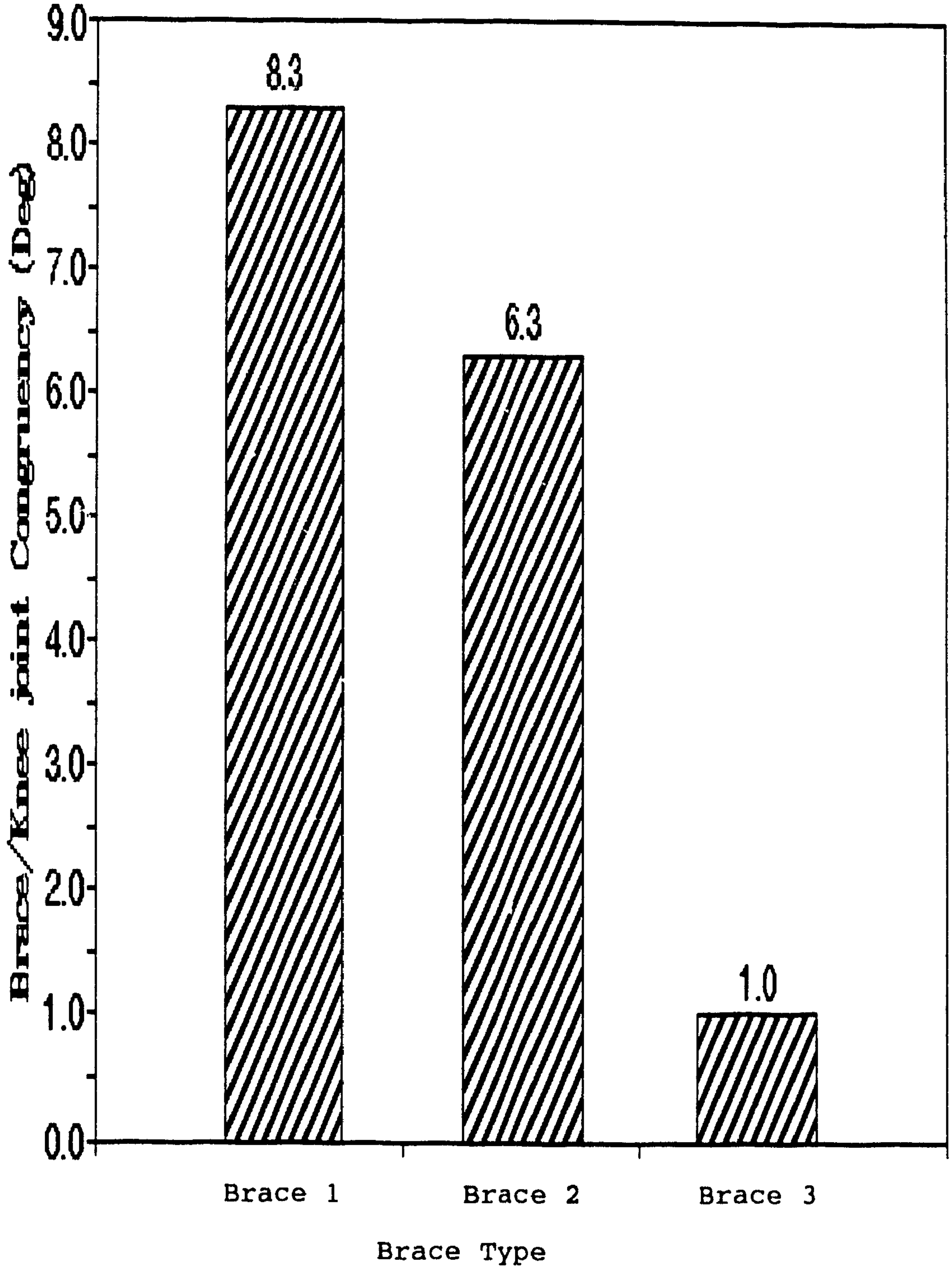


Figure 4.7: Braced Angle - Knee Angle During Kicking Task : Experiment II

(Degrees)
Vs
Brace Type



These results indicate that Brace 3 was the most effective in controlling knee extension during high velocity movement (kicking task). This result indicates that the congruency between Brace 3 and the knee joint is the highest. Brace 2 is the second best controller of knee extension during dynamic activity with Brace 1 demonstrating the least control. These results are not entirely concurrent with those from experiment one of this study, but this slight discrepancy (Brace 2 scoring better) may be due to the small sample size in this part of the study.

4.7 Analysis of Brace Fit : Experiment II

The final measurement involved the total migration of the brace during a ten minute jog. This was determined by calculating the difference between the initial position and the final position of the lateral hinge of the brace. The results of the test are presented in table 4.13 and figure 4.8.

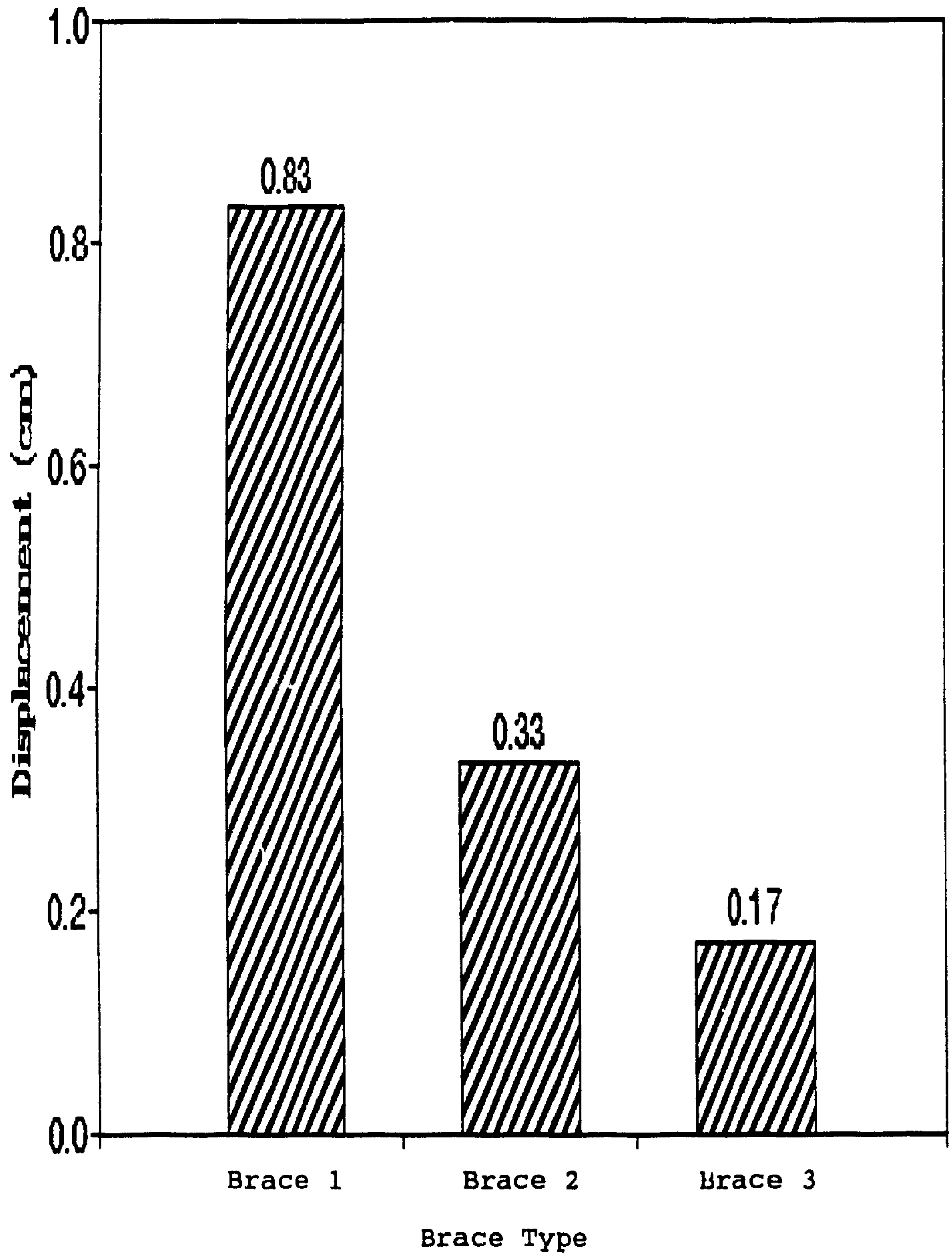
Table 4.13: Total Displacement of the brace: Running Task (cm.)
(mean, standard deviation)

	Brace 1	Brace 2	Brace 3
Total Displacement	.83 (.76)	.33 (.29)	.17 (.15)

The results in table 4.13 are similar to those demonstrated in the first part of this study. Brace 3 shows the least amount of migration during the running task followed by Brace 2 and finally Brace 1. Further analysis using a one-way Anova and a post hoc Tukey test revealed that there were significant differences between Brace 3 and Brace 1 at the $p<.05$ level. The results in table 4.13 are also presented graphically in figure 4.8.

The results of part two of this study reflect the results discussed in part one of this study for all tests. It can thus be concluded that for this particular study the subjects themselves have little influence on the results and that in fact the results are primarily governed by the type of brace and how closely the brace fits the contours of the knee joint.

Figure 4.8: Total Displacement During Running Task (cm) vs Brace Type : Experiment II



Chapter 5

DISCUSSION

5.1 Introduction

The factors representing the underlying premises for this research were as follows:

1) ACL damaged knees are characterized by specific physiological and anatomical deficiencies (Ahmed et al., 1987; Lipke et al., 1981; Markolf et al., 1990).

2) These deficiencies are responsible for the functional limitations and high incidence of re-injury amongst ACL injured athletes (Cabaud & Rodkey, 1985).

3) Functional knee orthoses were designed to minimize the anatomical deficiencies and thus prevent re-injury (Marquette, 1988).

4) Two factors that best quantify the efficacy of the knee orthosis in minimizing ACL anatomical and physiological deficiencies are: control of range of motion of the knee joint and the general fit of the knee brace (Lew et al., 1982; Walker et al., 1985; Shafer et al., 1988).

For the purposes of this research the most notable characteristic deficiencies of an ACL damaged knee were anterior translation of the tibia on the femur especially in the final 10-15 degrees of knee extension (Markolf et al., 1990; Ahmed et al., 1987) and internal rotation of the tibia on the femur (Kennedy & Fowler, 1971; Piziali et al., 1980; Lipke et al., 1981). These deficiencies result in a highly unstable knee joint since they allow for excessive movement occurring between the femur and the tibia. Unchecked, this instability can result in a high risk of re-injury to the knee joint since an unstable knee does not provide a solid base for high intensity, high force generating dynamic activity. Knee instability inhibits the transmission of energy along the kinetic chain resulting in less effective performance of all functional activities (McLeod, 1985).

The functional knee orthosis was designed to minimize the effects of the deficiencies of ACL damaged knees and in doing acts to prevent further injury. The question is ' how does one determine the efficacy of a knee orthosis?' This research project used two factors to establish the efficacy of the knee orthosis. The first factor involved control of joint range of motion. The literature clearly states that an ACL damaged knee demonstrates greater instability, reflected in increased movement between the tibia and the femur, in positions of knee extension and internal rotation (Markolf et al., 1990; Ahmed et al., 1987). Therefore, an effective knee orthosis would be one which restricted the amount of available knee extension and internal rotation of the damaged knee. In doing so, it should protect the ligament from further damage and provide a more stable joint necessary for dynamic activity and high loads. For this reason two specific measurements were analyzed. First, the amount of active range of motion (specifically, internal rotation and extension) present in the braced knee in comparison to the unbraced ACL damaged knee. Second, the amount of active knee extension present during a straight toe soccer kick with the braced knee was measured using a high speed video set on regular speed 30 fps.

One factor that affects the ability of the brace to control range of motion of the knee is how well the brace fits the contours of the knee joint.. A brace may be very effective in controlling range of motion in a static environment however, if the orthosis shifts position during dynamic activity due to a less than perfect fit, the efficacy of joint control will be lost and ultimately the function of the orthosis compromised. In order to evaluate this factor of brace fit a series of measurements were taken to establish the total migration of the knee brace during a specific running task.

It was the purpose of this research project to determine how effective each of the three braces were in controlling internal rotation ot the tibia on the femur and knee extension. Secondly, the effectiveness of this control during dynamic activitv was determined based on brace fit and how well it maintained its position during a dynamic running task.

5.2 Discussion of Results

The results from this study indicate that there is a significant difference between the three commercial braces in their control of range of motion and their capacity to maintain their position in relation to the knee joint during dynamic activity.

5.2.1 Results of Control of Active Range of Motion

The results for the active range of motion tests indicate that Brace 2 was the most effective controller of internal rotation while Brace 3 was most effective in controlling knee extension. Brace 1 was the least effective of the three braces in controlling joint range of motion.

The components of a knee brace that aid in the control of internal rotation include the following: 1) a close fitting tibial mold which comes into contact with the tibia and thus restricts rotation and 2) a tight fitting circumferential strap to hold the tibial mold and the brace in place (Berretta et al., 1985; Hunter, 1985). The results of part 1of this study indicate (although not significant) a trend where Brace 2 and Brace 3 were most effective in controlling internal rotation, because their tibial molds allowed for greater restriction of the tibia in relation to the femur. Brace 1 on the other hand did not have a tibial mold and most likely for this reason, the brace was less effective in controlling tibial rotation.

The results for control of knee extension indicate that during active range of motion Brace 3 was most effective in controlling full knee extension. Brace 2 was the second most effective controller of knee extension with Brace 1 being the least effective.

The components of a brace to provide control for knee extension includes the following: 1) a knee extension stopper, 2) non-elastic posterior popliteal strap and 3) a well fitting tibial mold. A knee extension stopper is a device that is built into the hinges of a knee orthosis preventing the orthosis from obtaining a position of knee extension past 15 degrees of flexion ie. it prevents full knee extension. This device is most effective when the brace fits well and thus the limited or blocked movement in the hinge can be transmitted to the actual knee joint so that the movement is also blocked at this level. The posterior popliteal strap and the well fitting tibial mold ensure that the brace is in constant contact with the specific anatomical contours of the knee joint so that the restrictions built into the brace can be transmitted to the knee joint itself (Coughlin et al., 1985; Berretta et al., 1985; Hunter, 1985).

Brace 3 included all the above mentioned components and therefore was able to restrict full knee extension most effectively. Brace 2 lacked a posterior popliteal strap although it does have a superior and inferior popliteal strap, however, these are not as effective in controlling knee extension. Brace 1 was the least effective in controlling knee extension because some subjects braces lacked an extension stopper and because the posterior straps were comprised of a very elastic component which allowed the knee to move away from the confines of the actual brace (Berretta et al., 1985; Hunter, 1985).

5.2.2 Results of Brace/ Knee Joint Congruency

The literature supports the idea that a functional knee brace must not only work under low force passive or active movements but also during high velocity dynamic tasks (Beck et al., 1985; Knutzen et al., 1983). Taking this fact into consideration, the kicking task was used as a test to determine the efficacy of the three knee braces in controlling knee extension during dynamic activity. The results indicate that Brace 3 was the most effective controller of knee extension during high velocity activity. Brace 1 was the second most effective while brace 2 demonstrated the least control of knee extension during this task.

The components of the orthosis that provide restriction of knee extension under dynamic loading conditions are the extension stopper and the posterior popliteal strap (Berretta et al., 1985; Hunter, 1985). As the knee joint progresses through the kicking motion the brace follows the same movement until it reaches 15 degrees of knee flexion where the extension stopper prevents the brace from going further. Theoretically the knee joint and the knee brace should move and stop as one, however the momentum of the tibia causes the knee joint to forcefully extend past the 15 degree flexion point. This movement of the tibia is restricted anteriorly by the knee brace and so the knee joint is forced to drop posteriorly through the brace allowing for further knee extension. The popliteal non-elastic posterior strap of Brace 3 helped to limit this posterior disengagement of the knee joint from the knee brace. In doing so, there is a greater and more effective brace/ joint congruency which allows for improved efficacy of brace function.

5.2.3 Results of Brace Fit

Some migration occurs in all three braces during the running task. However, the amount is insignificant for braces 2 and 3 and much more pronounced for Brace 1. This result indicates that Brace 2 and Brace 3 fit their respective subjects more accurately resulting in a better brace/ joint congruency. This is an important factor to consider since it is well documented in the literature that a brace can only be effective if it maintains its alignment with the knee joint (Lew et al., 1982).

The devices in Braces 2 and 3 which limit the migration of the brace during the running task are the close fitting tibial mold and the tight circumferential straps (Berretta et al., 1985). Brace 1 employs a circumferential strap but does not have a tibial mold to provide adequate grip on the tibia and as a result demonstrates the highest levels of migration during the running task.

In summary, Braces 2 and 3 proved to have the greatest efficacy in stabilizing the ACL deficient knee joint. In this case efficacy was determined by the ability to control internal rotation and knee extension while maintaining good anatomical alignment during active and dynamic activity.

From a functional perspective Brace 3 may be considered slightly more effective because of its better control of knee extension during the dynamic kicking task. Brace 1 scored low for all categories and may be designated the least effective of the three braces studied.

Chapter 6

CONCLUSIONS

The purpose of this research was two-fold. First, the characteristics of an ACL deficient knee as well as the fundamentals of functional knee braces were determined using an extensive literature review. Then this information was used to design a testing procedure to determine and compare the efficacy of three functional knee braces. Previous studies have shown that under low passive loads functional knee braces are effective in controlling anterior translation. This is considered an important mechanism because often it is under low loads (walking and pivoting, stair climbing) that the ACL damaged knee 'gives way' (Coleville et al., 1986). However, as the AAOS stated (Akeson et al.,1985) under higher loads this effective control of anterior translation is lost (Beck et al., 1986; Bassett et al., 1983). Therefore, in order for the brace to remain effective another means of control must be implemented during higher load, dynamic activity.

One of the ways to limit anterior translation is to avoid ranges of knee motion which are deemed more unstable and are characterized by an increase in translation of the tibia on the femur. In the case of the ACL damaged knee, previous studies by Markolf et al., (1990, 1976), Ahmed et al.,(1987) and Fetto et al., (1979) have shown that instability is more pronounced during the last degrees of knee extension and that this instability is further exaggerated by a coinciding increase in internal rotation. Therefore, it can be concluded that a functional knee brace will be more effective if it is able to control or limit knee extension and internal rotation during active or dynamic movement.

In the present study the criterion variable of active range of motion between the ACL damaged knee and the braced ACL damaged knee (for extension and internal rotation) was used as one measure of the efficacy of the knee orthosis. It was decided that a brace that limited full knee extension and internal rotation would provide more stability to the ACL damaged knee. The results of this study indicate that Brace 3 and Brace 2 were the most effective in fulfilling these requirements.

In order to further investigate this mechanism of range of motion control, a dynamic task was designed to measure the control of knee extension during high velocity movement. Subjects were asked to perform a straight toe soccer kick and the difference between the brace angle and the knee angle was measured. It was felt that increased instability during this movement due to a position of full knee extension could result in a high risk of re-injury since under normal circumstances (ie. during sports activities) the athlete would land on a joint which was not well aligned (anterior translated) resulting in a 'giving way' episode. The results in this study indicate that Brace 3 was most effective in controlling the extensor mechanism during high velocity activity.

The final criterion variable used in this research to determine the efficacy of functional knee braces was the measurement of 'brace fit' or the approximation of the brace to the contours of the knee joint. In this study a brace was designated as well fitting if it did not change position or migrate during a dynamic activity over a set period of time. The task of running for a ten minute period on a treadmill set at 6 MPH was used as a testing procedure for the measurement of brace displacement and ultimately brace fit. The results in this study indicate that Brace 3 and 2 migrated minimally during the running task.

This research protocol used the described criterion variables as a means of determining the efficacy of three commercial functional knee braces. This study differs from previous research in that it does not use the criterion variable of anterior translation as a measurement of brace effectiveness but rather uses measurements more appropriate for active and dynamic movements.

The results of this study indicate that there are significant differences in how the three braces being evaluated respond to the testing procedures. Initially, it was felt that there would be no significant difference between the three braces. As a result of this, the null hypothesis was proposed for each of the criterion variables. However, results indicated that there was a significant difference between the three braces for the following measurements:

1) knee extension of the ACL damaged knee - extension of the braced ACL damaged knee during active movement.

2) relative brace angle - relative knee angle during the kicking task.

3) total displacement of the brace during the running task.

The only measurement for which there was no significant difference between the groups was for the control of internal rotation. The fact that there was significant difference in the measurements of efficacy for the three braces indicates that for the criterion variables being evaluated, brace design plays an important role in how well a particular brace scores. The different characteristics of the braces are reflected in their results on the efficacy tests.

From this study it can be concluded that important components of a knee brace for dynamic control include: an extension stopper of 15 degrees, a non-elastic popliteal strap, a well fitting tibial mold and an appropriate suspension system for the brace (i.e circumferential straps). Brace manufacturers are faced with the dilemma of producing a brace which is light weight, comfortable and protective while at the same time able to withstand large forces being placed on the knee joint during high level dynamic activity. In addition, this brace must adhere to the non- uniform contours of the knee joint and surrounding musculature as this very surface undergoes a constant, repetitive jostling force during various dynamic activities. Even a well designed brace will prove to be ineffective if the alignment of the brace with the actual knee joint is not maintained (Lew et al., 1982).

In summary, this study determined a means of evaluating the efficacy of functional knee braces during active and dynamic movement. Previous studies have established the importance of controlling anterior translation under low passive loads (Hoffman, 1984; Beck, 1986) but few studies have indicated how a functional brace can be effective under active and dynamic loads. The control of anterior translation remains one of the key factors in effective functional knee bracing and further studies are needed to improve the mechanisms of controlling this instability. However, if researchers in orthopedics and sports medicine are going to improve design of functional knee braces further research must be carried out in the dynamic setting. Research designs are needed to evaluate the efficacy of knee braces during more progressive activities such as basketball and football. Further studies are needed to correlate efficacy measurements with knee stability, subjective rating scales and activity levels. As more people become involved in sporting activities and the risk of injury and subsequent re-injury increases, greater demands will be placed on researchers and sports medicine professionals to develop effective means of protecting unstable knee joints while allowing return to previous activity levels.

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APPENDIX

Biomechanics Laboratory
McGill University

Informed Consent Form

The study you have volunteered to participate in is designed to evaluate anterior cruciate ligament deficiencies. There are three distinct elements to the study. Two of these will involve the evaluation of functional knee braces, the third will evaluate the biomechanical characteristics of cruciate dysfunction.

The Genucom Knee Analyzer is a non-invasive research tool which will be used to gather a portion of the data required for analysis. During the Genucom assessment various forces will be applied to both knees by the examiner in a series of clinical tests. A maximum force of 33 lbs will be applied to the joint and the thigh muscle will be restrained by the device. Further tests involving measuring the amount of movement in the knee joint with and without the brace and the amount of movement during a kicking task will also be evaluated. Finally, you will be asked to run on a treadmill for ten minutes in order to determine how much displacement occurs between the brace and knee joint.

It is important to appreciate that any one or series of these proposed tests may cause some minor discomfort to you. Therefore your participation in this study can be discontinued at any time throughout the protocol by simply communicating your intention to the technician. As such, you may refuse to complete one or all of the proposed tests.

All results obtained in this study become the property of the McGill Biomechanics Laboratory. Confidentiality will be respected for all subjects involved in the study. The results and interpretation of the evaluation will be available to you at the completion of the study.

I have read and understand this informed consent form. My signature below reflects my consent to be a participant in this study.

Signature: ______________________________

Date: ______________________________

Address: ____

Telephone: ____________________