AN EVALUATION OF THE EFFICACY OF THREE FUNCTIONAL DE-ROTATIONAL KNEE BRACES IN CONTROLLING INSTABILITIES CHARACTERISTIC OF AN ACL DEFICIENCY

by

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ABSTRACT

The purpose of this investigation was to objectively evaluate whether three functional de-rotational knee braces stabilize an anterior cruciate ligament (ACL) deficiency. The subject sample consisted of fifteen males and females with a unilateral ACL deficiency. The data for each subject was obtained using the Genucom Knee Analyzer. A right knee-left knee anterior laxity difference of 3mm or greater served as a subject inclusion parameter for protocol completion. The inclusion criteria reduced the subject sample to a total of eleven.

The study consisted of a randomized block design. The experimental design consisted of three parts: (1) an investigation of translational stability, (2) an investigation of rotatory stability, and (3) a comparison between the three braces.

The analysis involved a one way ANOVA of the criterion variables; anterior laxity (ALAX), anterior midrange stiffness (AMRS), anterior endrange stiffness (AERS), internal laxity (ILAX), and translation of the lateral tibial plateau (TLTP).

The AMRS characteristics differed significantly (alpha=0.05) at 20° flexion. The results were the following: -10.00±9.78 N/mm for brace 1, -2.86±7.2 N/mm for brace 2 and -41.02±14.79 N/mm for brace 3. The values evaluated for ALAX, AERS, ILAX, and TLTP profiles did not differ significantly between knee braces.

ABSTRAIT

L'objet de cet étude à pour but d'évalué objectivement la fonction de trois ortheses, qui sont conçu pour stabilizer une rupture du ligament croissé antérieur (LCA). En tout, l'étude comprends quinze sujets et ils ont démontrer une rupture du ligament croissé antérieur sur un genou seulement.

Les résultats pour chaque sujet étaient obtenu avec le Genucom. Une différence du deplacement antérieur de 3mm entre le genou gauche et droit à servi comme un protocol pour sélectionner les sujets. Ce protocol à reduit la nombre de sujets de quinze à onze personnes.

L'étude était diviser en trois parties: (1) un diagnostic pour les instabilities du translation, (2) un diagnostic pour les instabilities de la rotation, et (3) une analyse pour déterminer la différence entre les trois ortheses. Une analyse de ANOVA (un sens) était employer pour les variables suivants: laxité anterieur (LA), rigidité de mi-distance antérieur (RMDA), rigidité de fin-distance antérieur (RFDA), laxité interne (LA), translation du plateau tibial latéral (TPTL).

Les résultats ont demontrer qu'il y avait une différence significative entre les trois ortheses pour la compliance anterieur au milieu, à 20° du flexion (alpha=0.05). Les résultats sont les suivants: -10.00±9.78 N/mm pour l'orthese #1, -2.86±7.2 N/mm pour l'orthese #2, et -41.02±14.79 N/mm pour l'orthese #3. Il n'y avait pas de différence significative entre les trois ortheses pour les mesures de ALAX, AERS, ILAX, et TLTP.

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CHAPTER I

INTRODUCTION

Controversy concerning the ability of functional knee braces to effectively stabilize anterior cruciate ligament (ACL) deficient knees may be attributed to three major factors. Foremost many researchers have approached knee brace assessment subjectively. Wellington, evaluated the Lennox Hill knee brace as a treatment protocol for patients with cruciate and collateral ligament damage. The results of this treatment were qualitative in nature and based on the patients opinion of stability and comfort. Nicholas (1983), documented the percentage of Lenox Hill braces prescribed between 1976-1980 and concluded that the number of perscriptions, which totalled nearly 9000 in the United States, demonstated the effectiveness of the brace. More recently, researchers recognize the need for the quantification of objective data. Bassett (1983), Beck et al., (1986), and Colville et al., (1986) disagree with the methodology of the two prior studies and stressed the importance of obtaining objective data as a criteria for evaluating functional knee braces effectively.

A second reason for confusion regarding knee brace efficacy stems from the inability to apply functional forces during a clinical evaluation. Internal forces generated in weight bearing activities are far greater than the loads elicited clinically

(Segal, 1983), however, researchers are limited to evaluating brace efficacy under low clinical forces for fear of causing structural damage to the passive restraining strutures.

Finally, a standard means of assessing an ACL deficient knee clinically does not exist. If the effectiveness of established protocols in the assessment of ACL dysfunction is questionable then it follows that the application of such tests to determine brace efficacy is also questionable.

In summary, subjective evaluations, inadequate functional forces and the absence of standard tests are three factors which contribute to the uncertainty which surrounds the efficacy of functional knee braces in controlling an ACL deficiency. This suggests that additional studies are needed to develop an adequate methodology to objectively evaluate whether braces stabilize an ACL deficiency and more importantly protect the knee joint from developing additional injuries.

1.1 NATURE AND SCOPE OF THE PROBLEM

It is well established that clinical investigations have identified the ACL as the most frequently torn ligament within the knee joint (Mueller, 1985). The frequency of injury to this structure is a reflection of its functional importance. Several authors including Lipke et al., (1981), Butler et al., (1980), and Fukubayashi et al., (1982) describe the ACL as one of the primary structures in maintaining knee joint stability. Hence the ACL is a major contributor in establishing the dynamics which maintain the functional congruity of the knee joint. These dynamic characteristics include: controlling laxity, absorbing joint energy and controlling joint alignment (Akeson, et al., 1985).

Based on the functional importance of the ACL and how damage to this structure significantly changes the integrity of the joint we can appreciate the importance of effective knee bracing. The multiple factors which characterize an ACL deficiency substantiate the complex mechanisms which must be accomodated by a brace design if it is to stabilize and protect the knee joint.

A number of studies have attempted to identify characteristics of a deficient ACL. These deficiencies are reflected by translational and rotational instabilities of the damaged joint. An investigation by Noyes et al., (1980) documented the ACL as the primary restraint (86%) to the anterior drawer. As such, anterior translation is often considered to be reflective of ACL dysfunction. The restraining properties of the ACL are not only responsible for inhibiting anterior translation but also for absorbing energy transferred through the joint. Studies by Shino et al., (1987) and Markolf et al., (1976; 1984) characterized the compliance of the joint as a parameter describing ACL dysfunction.

Along with controlling the anterior translational movements of the tibia there is a general agreement within the literature that the ACL also provides a secondary restraint to rotatory movements (Butler et al., 1980). Mueller and coworkers (1985) demonstrated the coupling effect of increased internal rotation and increased anterior translation, clinically termed as anterior-lateral rotatory instability, that characterize the ACL injury. The authors identified an excess anterior translation of the lateral tibial plateau during internal rotation for a deficient ACL knee.

In light of what has just been presented it is increasingly clear that for an orthosis to be beneficial it must provide two basic constraints. First, the orthosis must compensate for the translational and rotational instabilities and secondly it must compensate for the lacking stress-strain relationship of the tibiofemoral joint. The reasoning behind this is simple; controlling joint laxity (translational and rotational instabilities) minimizes the excess movement between the tibia and the femur while, controlling the compliance of the joint (stress-strain relationship) increases the mechanical stiffness within the joint. Together, both these functions protect the remaining structures within and surrounding the knee joint from further damage.

In addition to providing these two basic constraints an orthosis must also replicate the anatomical motion for an intact knee joint. Walker et al., (1985) implied that this included reproducing the "rollback" of the femur relative to the tibia and externally rotating the tibia, both during flexion . Furthermore, Marquette (1988) indicated that the orthosis should correct the medial and posterior shift of the instant center in the transverse and sagittal plane, which occur when the ACL is damaged or absent. Thus, as Mansour (1985) suggested to produce the optimal functionality required from an orthosis, implies incorporating the biomechanical properties of an ACL into an external device so that it mimics normal ACL function .

1.2 PURPOSE OF THE STUDY

Thus the purpose of this study is twofold. First, to objectively evaluate whether three functional de-rotational knee braces stabilize an ACL deficiency. Specifically their ability to control translational instabilities in a quasi dynamic protocol (i.e. throughout a range of motion and with clinical loads ranging from 130 N to 140 N) and rotational instabilities in a static state. Secondly, to objectively evaluate which brace most effectively controls the characteristics of the injury.

1.3 STATEMENT OF THE PROBLEM

The problems to be investigated in this study are the following:

a. Is there a significant difference between anterior laxity values obtained throughout a range of motion for the involved knee when braced with three different othoses?

b. Is there a significant difference between anterior stiffness values obtained throughout a range of motion for the involved knee when braced with three different orthoses?

c. Is there a significant difference between internal rotatory laxity values obtained for the involved knee when braced with three different orthoses?

e. Is there a significant difference between anterior translation of the lateral tibial plateau obtained for the involved knee when braced with three different orthoses?

1.4 HYPOTHESES

1. There will be no significant difference between anterior laxity values obtained at four flexion angles for each brace.
2. There will be no significant difference between anterior stiffness values obtained at four flexion angles for each brace.
3. There will be no significant difference between anterior laxity values obtained by brace 1, brace 2 and brace 3.
4. There will be no significant difference between anterior stiffness values obtained by brace 1, brace 2, and brace 3.
5. There will be no significant difference between internal laxity values obtained by brace 1, brace 2 and brace 3.
6. There will be no significant difference between anterior translations of the lateral tibial plateau obtained by brace 1, brace 2 and brace 3.

1.5 Limitations and Delimitations

Limitations:

1. A limitation of this study is that the contribution of the muscles surrounding the knee joint were not monitored by EMG during the evaluation. The design of the testing protocol assumes that the muscle activity is minor and is controlled for by visual and manual monitoring.

2. A second limitation is that the subject sample may not all be isolated ACL deficient knees. The stability of the knee joint is maintained by the synergistic interaction of many structures and hence damage may have occured to more than one structure.

Delimitations:

1. A delimitation of this study is that clinical loads are applied to the knee joint as it is maintained in a static position. These applied forces ranging from 100N to 150N do not duplicate the magnitude of the actual functional translational forces which can range from 300N to 500N during an activity. It should also be noted that if functional forces were applied to a knee joint in a static position it could cause structural damage to the passive restraining structures and therefore should only be applied during an activity which elicits the active restraining forces.

2. Only three braces are being analysed in this study and

this is small percentage of the actual number of functional braces available on the market.

1.6 Abbreviations and Definitions

ACL - Anterior Cruciate Ligament

PCL - Posterior Cruciate Ligament

MCL - Medial Collateral Ligament

LCL - Lateral Collateral Ligament

ALRI - AnteroLateral Rotatory Instability

(Identified by an excess anterior translation of the lateral tibial plateau during internal rotation)

AMRS - Anterior MidRange Stiffness

(Calculated as the ratio of force/displacement measured midrange between 30N and 70N)

AERS - Anterior EndRange Stiffness

(Calculated as the ratio of force/displacement measured endrange between 120N and 130N)

ALAX - Anterior LAXity

(Obtained at a force value of 125N)

ILAX - Internal LAXity

(Obtained at a torque value of 8Nm)

TLTP - Translation of the Lateral Tibial Plateau during internal rotation

(Obtained at an internal rotatory value of 15°)

ANT/POST ANTerior/POSTerior; this describes a direction perpendicular to the long axis of the tibia and runs parallel to the sagittal plane

Isolated ACL deficiency - Identified by a positive drawer sign of grade 2 or greater and confirmed by an arthroscopic diagnosis.

Laxity - Describes the translation of the tibia in relation to the femur and is measured in mm or degrees.

Stiffness - Reflects the viscoelastic properties of the ligaments and the ability of the ligament to absorb the energy which transferred through the tibiofemoral joint. This value is obtained from the inverse slope of a load-displacement curve and is measured in N/m or Nm/degrees.

CHAPTER II

REVIEW OF LITERATURE

2.1 INTRODUCTION

The function of a knee orthosis specifically designed to stabilize an ACL deficiency is determined by many factors. These factors include anatomy and biomechanics of the ACL, knee joint dynamics, and characteristics of an ACL deficiency. Since the purpose of this study was to objectively evaluate the efficacy of knee orthoses in stabilizing translational and rotational instabilities reflective of an ACL deficiency, the following concepts are addressed in this section: (1) the definition of ACL function and characteristics reflecting an ACL dysfunction, (2) the features of an ideal functional orthosis and finally (3) testing protocol designed to evaluate functional knee braces.

2.2 Characteristics of a Deficiency

The knee joint is maintained functionally through the synergistic action involving muscular dynamics, articular surfaces, and ligament restraints. The unique function of the ACL provides an essential supportive structure by which the complex nature of the knee is maintained.

Noyes and coworkers (1978) reported that the ACL provides an average of 87 percent of the total resisting force in the anterior drawer. Similar results were obtained in a follow up experiment carried out by Butler, et al., (1980). The study was designed to rank the order of importance of capsular and ligamentous structures in restricting anterior-posterior translations. The tests were conducted in a similar fashion to the original study except that restraining forces in the second study were not only measured at 90° but also at 30° knee flexion. The results indicated that the ACL provided 85.1 ± 1.9 % and 87.2 ± 1.6 % of the total restraining force to anterior translation at 90° and 30°, respectively. This study established the distinction between primary and secondary restraints. It was concluded that during an anterior drawer, the ACL is a primary restraint.

Ahmed, et al., (1987), used a buckle transducer to obtain ligament tensions and reported that among four major ligaments measured (ACL, PCL, MCL, LCL), substantial tension was generated only in the ACL when the tibia was translated anteriorly by 5mm. Thus this study further supports the concept of the ACL as a primary restraint in anterior translation. The tension patterns generated in response to tibial axial rotation were complex and varied between specimens. As such, the ACL did not provide primary restraining action during axial rotation. However, the tensions generated seem to implicate the ACL as a secondary restraint.

Based on these two studies and several others (Markolf, 1976; Mueller, 1985; Shino, 1987; and Marquette, 1988) it was demonstrated that an ACL dysfunction results primarily in translational instabilities and secondly in rotational instabilities. Thus the dynamics which maintain the functional congruity of the knee joint for an uninjured ACL characterize the translational and rotational instabilities which reflect an ACL deficiency. These characteristics include: knee laxity, knee stiffness and joint dynamics.

2.2.1 Knee Laxity

Many authors agree that knee laxity describes the translation of the tibia in relation to the femur (Kennedy and Fowler, 1971; Markolf, et al., 1976; Hsieh and Walker, 1976; Lipke, et al., 1981; Fukubayashi, et al., 1982; Shino, et al., 1987; Markolf, et al., 1984). However, it must be considered that a majority of these studies, with the exception of those done by Shino et al., (1987) and Markolf et al., (1984), were in-vitro assessments. Therefore, the dynamic involvement of the surrounding musculature was removed resulting in translations which may not reflect an in-vivo situation. More in-vivo studies are required to provide laxity data in order to characterize an ACL deficiency.

Biomechanically, the tibiofemoral joint contains six degrees of freedom and thus elicits more than one type of translation. Markolf, et al. (1976) used the term anterior-posterior laxity or total laxity to describe the displacement between the tibia and the femur in the sagittal plane. Rotatory laxity describes the tibial torsion and varus-valgus laxity described the displacement between the tibia and femur medially and laterally. All three laxity measures were determined in a similar fashion. Tangents were constructed for the upper and lower portions of a force-displacement or moment-rotation curve at the following forces and torques: anterior-posterior displacement, ± 100N; tibial torsion, ± 8N and varus-valgus angulation, ± 29Nm. A third tangent was constructed at the neutral or middle portion of the curve. The points at which the tangents intersected represented the breakpoints of the curve and the distance between them defined laxity. Markolf (1976) admitted the impossibility of determining a neutral or midrange position of the knee from the generated force-displacement or moment-rotation curves. This neutral position would have allowed a description of laxity values according to the direction of the applied force or torque. Shino et al., (1987) emphasized the importance of obtaining a neutral position. The neutral position of the knee for his study was the point along the force-displacement curve where no external load was applied to the tibia. It was assumed that the anterior portion of the curve was a greater reflection of the ACL functionally than the total laxity measurement. This assumption was based on the reasoning that secondary structures may be affecting the posterior aspect of the curve and therefore this portion of the curve does not accurately reflect the integrity of an isolated ACL.

The method commonly used to determine the effect of ligament damage on knee laxity involves measuring the translation before and after selectively cutting various ligaments. Several studies have shown significant increase in anterior-posterior laxity after severing the ACL (Lipke, et al., 1981; Fukubayashi, et al., 1982; Mueller, 1985; Hsieh and Walker, 1976; Gollenhon, et al., 1987). Using sequential cutting of the structures Hsieh and Walker (1976) found that laxity always increased. However, it was observed that the forward translation or dislocation of the tibia only changed significantly once the ACL was cut. The average anterior-posterior (total) laxity values for normal knees at 0° and 30° flexion was 8.6mm to 8.4mm, respectively. After cutting the ACL the laxity values increased to 10.7mm and 13.4mm.

Less than half of the studies previously mentioned obtained an increase in rotatory laxity. Lipke and coworkers (1981) investigated internal-external laxity values at five positions of knee flexion (0° to 40° in 10° increments) with an applied force of 224Nm. The most significant results appeared at 20° flexion. Internal laxity significantly increased after the ACL alone was sectionned. The laxity increased further after sectionning a few selected lateral structures. External laxity showed a significant difference only after the lateral structures were sectionned. Even a second test sequence in which the ACL was cut last, showed a significant increase in internal laxity but not in external laxity. These results strongly support the notion that internal laxity may characterize ACL dysfunction to a greater degree than external laxity.

The results obtained by Lipke contradict the findings made by Hsieh and Walker (1976). This study, performed at 30° flexion, demonstrated a significant increase in internal laxity after the medial collateral was severed, followed by the anterior cruciate. Interestingly enough, in the reverse order of cutting the anterior cruciate first had no significant effect in increasing internal laxity until after the medial collateral was severed. These findings, describing the function of the anterior cruciate and medial collateral ligament (MCL) as a resistant coupling effect, can be explained by their anatomical locations. During internal rotation the axis of transverse rotation is on the medial side and hence the ACL and MCL are the structures most effective in limiting translation along that axis.

It is difficult to discern which of the previous two studies describes the involvement of the ACL in controlling internal rotation of the knee. However, the internal rotatory phenomenon illustrates the role of the ACL as one of the structures involved in maintaining joint stability and further clarifies the importance of the ACL as a secondary restraint to internal rotation.

The two preceeding studies measured rotatory laxity when the knee was flexed at 20° and 30°. A number of studies disagree with measuring tibial torsion at flexion angles appoaching full extension. As the knee nears full extension the femoral condyles may impinge upon the tibial plateaus, limiting torsional movement. Thus rotational measurements are often obtained when the knee is flexed at 90°.

Several studies have measured anterior laxity and internal rotatory laxity at clincial loads. Shino and coworkers (1987) applied an anterior force of 200N while Fukubayashi, et al., (1982), Markolf, et al., (1976), and Hsieh and Walker, (1976) applied anterior forces ranging from 100N to 125N. The reason for applying clinical loads was that functional loads ranging from 300N to 500N (Lipke,1981) could not be replicated in an in-vivo knee without endangering the integrity of the knee joint. The ligaments alone do not provide enough resistive tension to restrain large forces and in order to do so, the interaction of the surrounding muscles of the knee joint is required. Internal rotatory laxity of the tibia has been measured at clinical torques ranging from 5.5Nm (Hsieh and Walker, 1976) to 8Nm (Markolf, et al.,1976). Again these torque values resemble those applied in a clinical environment for ethical reasons. In summary, the structural and functional abnormalities associated with an ACL disruption result in an increase in translation and rotation of the tibia. It has been observed fairly extensively that anterior laxity and internal rotatory laxity both manifest the integrity of the ACL.

2.2.2 Knee Stiffness

It is apparent that the anterior cruciate ligament is a primary restraint restricting translational instabilties and a secondary restraint inhibiting rotational instabilities. One method of quantifying the restraining action of the ACL is by measuring joint laxity. However, another parameter which reflects the viscoelastic properties of the ACL and the ability of the ligament to absorb energy transferred at the joint, is determined by measuring joint compliance.

Markolf et al., (1976) described joint compliance as stiffness. For this particular study stiffness was calculated by determining the change in force over the change in displacement, from an anterior-posterior force-displacement curve. The force-displacement relationship of the ligament produces a nonlinear load deformation curve (Frisen, et al., 1969). Thus implying that different components come into action at different stages of deformation. These different stages of deformation have been described by two types of stiffness. Markolf, reported that anterior endpoint stiffness was influenced most by a severed ACL. This parameter was equated at a force value of 100N, which was the suggested force during a Lachman test. The average anterior endpoint stiffness values for non injured knees at 0°, 20°, 45° and 90° of knee flexion were 11.8 ± 7.0 N/mm, 6.6 ± 2.5 N/mm, 7.8 ± 4.0 N/mm, and 14.3 ± 15.7 N/mm, respectively.

Shino and coworkers (1987) also investigated the compliant properties of the anterior cruciate, however a force value of 50N was adopted. It was believed that this midrange value reflected the restraining force of the ACL, whereas endpoint stiffness was affected by secondary restraints, such as the menisci and joint capsule. The study employed a newly developed apparatus which measured anteroposterior stability of the knee up to forces of

250N, applied at 20° flexion. Measurements reported the average anterior stiffness values, of seven intact knees as decreasing from 2.4 ± 0.6 N/mm to 1.2 ± 0.5 N/mm after the anterior cruciate ligament was sectionned.

Shino's concept of secondary restraints affecting anterior endpoint stiffness was in agreement with a study done by Butler, et al. (1980). He concluded that not only is the ACL the primary constraint to the anterior drawer but that the secondary restraints may block clinical laxity tests, such as the Lachman test. It was further suggested that the secondary restraints become compromised only after higher clinical forces were applied.

Thus anterior stiffness can be evaluated at two stages of the force-displacement curve. Either at a stress value of 50N, where it is hypothesized that secondary structures have not yet come into action, or at a stress value of approximately 100N, which is the endpoint recommended during a Lachmans test.

Unfortunately, very few studies have investigated the restraints provided by the anterior cruciate ligament during internal-external rotation. This is probably due to the fact that the anterior cruciate ligament is not a primary resisting structure during axial rotation of the tibiofemoral joint. One of the few studies which considered this characteristic as a reflection of the ligaments' integrity was published by Markolf, et al., (1976). During the investigation, tibial rotatory stiffness was evaluated at a torque of 8Nm and resulted in internal rotatory stiffness values of 2.3 ± 0.6 Nm/deg, 2.6 ± 0.7 Nm/deg, 2.7 ± 0.9 Nm/deg, 2.8 ± 0.7 Nm/deg, 2.6 ± 0.6 Nm/deg and 2.5 ± 0.6 Nm/deg for flexion angles 0°, 10°, 20°, 45°, 90°, and 135°, respectively. The external rotatory stiffness values were not significantly different from the internal values.

Another strategy used to determine rotatory stiffness patterns was employed by Louie and Mote (1987). The study investigated the relationship between activating different muscle groups crossing the knee joint and the rotatory stiffness parameters of the joint. The results showed internal stiffness values ranging from 3.0 to 6.2 Nm/deg for normal knees flexed at 90°. An analysis of the data after the activation of a combination of quadriceps and hamstring muscle groups showed an increase in joint stiffness with increased numbers of active muscles.

In summary, several investigations have addressed joint stiffness as a parameter describing the compliant properties of the knee joint. There is a general concensus within the literature that the ACL contributes to joint translational stiffness and, to a lesser degree, to joint rotatory stiffness. However, the quantification of the contribution of the non-passive musculature to knee joint rotatory stiffness is significant and as a result, must be controlled or considered a potential limitation when performing a passive rotatory test.

2.2.3 Joint Dynamics

The final method of describing an ACL deficiency is by evaluating the dynamics of the tibiofemoral joint. Segal and Jacob (1983) described the passive control of the knee joint three dimensionally. Their findings include the following: (1) in the frontal plane (figure 1) the femur and the tibia are incorrectly aligned anatomically and form a physiological valgus of 174 degrees, (2) in the sagittal plane (figure 2) the alignment of the femur and tibia form a vertical line which serves as a reference of 0 degrees flexion and (3) in the horizontal plane (figure 1) the femur is held immobilized under the femur and rotates 5 degrees laterally during the movement from flexion to extension.

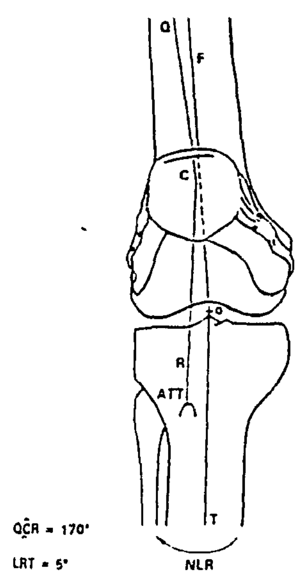


Figure 1.

Alignment of the tibia and femur in the frontal and horizontal planes (Segal & Jacob, 1983).

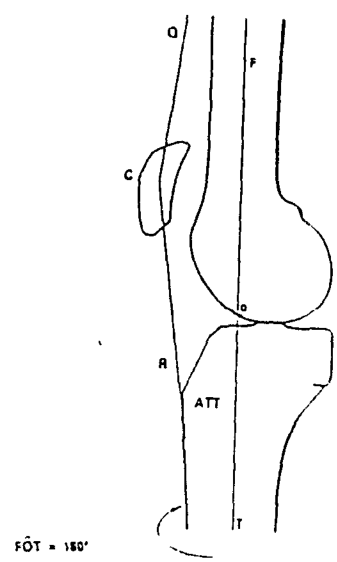


Figure 2.

Alignment of the tibia and femur in the sagittal plane.

In summary, the synergistic interaction of the capsular and ligamentous system maintains the passive control of the knee joint.

Joint dynamics are characterized by the motion of the femur through a series of three dimensional instantaneous axes. The calculation of the instant center is a method of identifying whether the dynamics of the tibiofemoral joint have been altered and represents the motion between the articulating sufaces of the tibia and femur in all three planes (Rouleaux , 1876). Marquette (1988) confirmed that the instant center of the knee moves medially and posteriorly from its normal position, when the ACL is absent. This shift into the medial compartment of the knee joint results in lengthening the lever arm to the lateral tibial plateau and consequently increases the anterior subluxation of the lateral tibial plateau.

There is an agreement within the literature regarding bilateral symmetry of knees. Shino et al., (1987) tested 61 normal subjects and obtained no significant difference in anterior laxity or anterior stiffness measurements between right and left knees. This was further confirmed by Hoshizaki and Sveistrup (1985).

Obviously, the anterior cruciate ligaments' susceptibility to injury is a result of its unique action in stabilizing the knee joint. Anatomically, the ACL is comprised of two discrete bundles of fibre: anteromedial band (AMB) and posterolateral band (PLB) (Girgis et al., 1975). Girgis and coworkers reported that the orientation of the bony attachments of the AMB and PLB are primarily responsible for the dynamics of the ACL through the range of motion. Arnoczky (1983) also investigated the function of the discrete bands of the ACL. While functionally the PLB is taut when the knee is extended and the AMB is taut when the knee is flexed, the ACL consists of a continuum of fascicles of which different parts are taut through the range of motion. This suggests that the resistance of the ACL is not constant as the tensile strength of the ligament varies throughtout a range of motion.

McLeod (1985) discussed at which points throughout a range of motion the ACL is under a strain. Because the anterior cruciate ligament is angled between the medial face of the lateral femoral condyle and the anterior portion of the proximal tibial surface between the plateaus, its spatial orientaton changes at different flexion angles. It appears that the anterior cruciate ligament enters the tibial surface at an angle of about 30° to the slope of the tibial surface when the knee is at 90° flexion and the angle increases between 40° and 45° as the knee moves into full extension. Furthermore, the force created by the anterior cruciate can be resolved into two components: (1) one component in line with the long axis of the tibia directed toward approximating the joint and (2) a second component at a right angle to the first component in the anteroposterior direction. Thus, these two components would serve to first compress the joint and secondly, prevent anterior motion of the tibia in relation to the femur. It was reported that approximately 86% of the anterior cruciate force would be directed toward inhibiting anterior motion when the knee is flexed at 90°. However, in full extension the tension force decreased to 70% for the component preventing anterior motion. These findings seem to suggest a greater tensile strength at 90° flexion as opposed to the knee joint in full extension.

Studies using a buckle transducer to obtain ligament tensions found that the ACL produced the greatest tension between 0° and 40° and at 90° flexion. Lew and Lewis (1982) reported forces of the anterior cruciate ligament obtained from a calibrated buckle transducer for three normal knees. The results determined the greatest restraining force to be between 0° and 30° and at 90° flexion.

Similarly, Ahmed, et al., (1987) measured tensions generated by the anteromedial band of the anterior cruciate ligament of 30 specimens throughout a range of flexion angles (40°-90°). The results showed the ACL generated the greatest amount of tension in response to an increasing anterior translation of the tibia at both 40° and 90° flexion. The tension pattern generated in response to tibial axial rotation was far more complex and varied considerably between specimens. In spite of these variations, the ACL had the greatest tension at 40° flexion and was frequently elicited in internal rotation only.

In order to describe joint dynamics, specifically the anatomy and function of the anterior cruciate ligament, four flexion angles have been identified as generating the greatest amount of tension in response to an increasing anterior translation and axial rotation. The four flexion angles are:

90°, 40°, 30°, and 20°. The preceeding sections identified the fundamental characteristics of an ACL insufficiency. If an orthosis is to be beneficial in stabilizing and protecting an ACL deficient knee joint, it must provide constraints compensating for these types of instabilities. The following sections describe testing protocols designed to evaluate the efficacy of functional knee braces.

2.3 Testing Protocol

Functional knee braces are specifically designed to provide functional stability of the knee joint. One of the major problems in determining the efficacy of functional knee braces is defining how the brace effects the stabilizing components, such as: ligamentous restraints, weight-bearing compressive forces, muscular forces and neuromuscular mechanisms. Furthermore, this problem leads to many questions. For example, how should a brace be evaluated under varying levels of activity? Should the surrounding musculature be activated during the evaluation? Finally, how should the protocol isolate and identify the different ligamentous ruptures? Because of the difficulties involved in answering these questions two types of testing protocols have been developed. These protocols include both static and dynamic testing conditions. The static condition assesses the orthosis' ability to limit translational and rotational knee joint movement elicited by passive structures such as ligaments, articulating surfaces, and menisci. Clinical loads are applied during static testing in order to avoid further damage to the passive structures. The dynamic condition focuses on the efficacy of the knee brace during activity and the involvement of the surrounding musculature as a major restraint limiting knee joint motion.

2.4.1 Static Testing

Practically all the data quantifying knee brace efficiency has been collected while the knee joint was in a static angular position. In many cases the knee brace was capable of decreasing some of the laxities associated with ACL lesions.

In a recent study, Marquette (1988) reported the biomechanical requirements of the orthotic design necessary to stabilize anterior cruciate ligament injuries. He identified two important features that must be incorporated in the design of the orthosis. First, the orthosis should generate the normal anatomical motion between the tibia and femur. To achieve this the orthosis should mimic the biomechanical properties of the ACL, which is to effectively transfer force from the anterior superior tibia to the posterior distal femur (figure 3). As illustrated, no problem exists in applying a force to the anterior superior tibia, however, because of a large amount of circulatory anatomy at the area of the posterior distal femur, an alternative method of transferring force must be employed by the orthosis. A method which is thought to do this is the two point pressure system (figure 4). This system resists anterior joint motion by creating a posteriorly directed force at the joint center. This is accomplished by applying a pressure point posterior and as far distally as knee flexion will allow and a second point to the anterior superior thigh thus causing a lever arm system of stabilization at the joint center.

The second important feature of the orthosis is its ability to transfer enough force to prevent further injury of the ACL or injury to secondary structures, which become stressed in the absence of the ACL. The brace is designed to achieve this by a four point pressure system (figure 5). The two point system previously described is thought to resist anterior motion and transfer force from the tibia to the femur. A third point located on the anterior superior tibia transfers force to the joint, minimizing abnormal anterior motion of the tibia caused when large forces are applied. One such force includes the anterior tibial force generated by the quadricep muscles. Finally the fourth point located at the distal posterior gastrocnemius simulates the function of the hamstrings, by decreasing the anterior inertial energy generated when the leg reaches terminal swing.

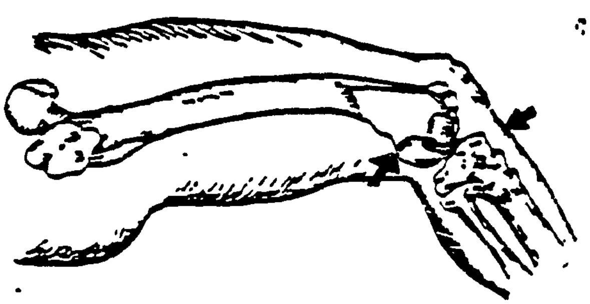


Figure 3. Ideal System

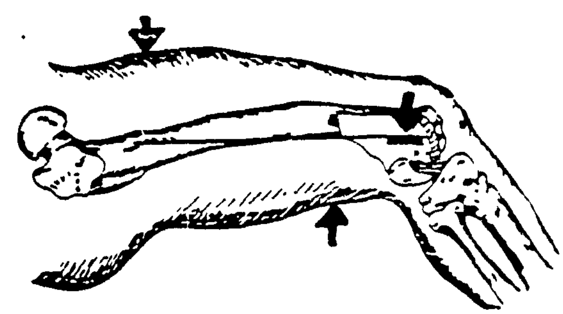


Figure 4. Two Point Pressure System

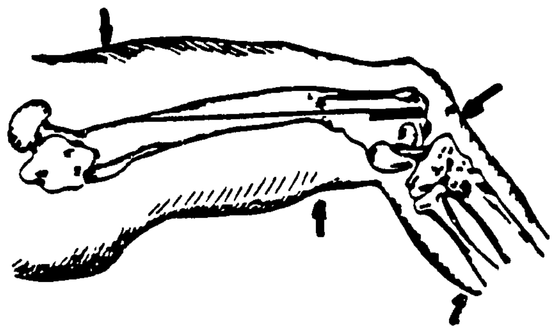


Figure 5. Four Point Pressure System

The above two features are the basic principles in designing an ideal orthosis. However there is little objective data available quantifying the efficacy of this design. Nicholas (1983) reported that the Lenox Hill derotation brace was designed such that the sliding axis of the brace corresponds to the natural axis of movement in the knee, thus enabling the orthosis to compensate for anterior and rotatory instabilities. However a study performed by Colville, et al., (1986) observed the Lenox Hill brace failing to significantly reduce anterior laxity, although it did increase resistance to anterior displacement. He also found that on average the rotatory instability was reduced one grade by the brace, yet this was a subjective analysis. In a study by Knutzen, et al., (1984) a comparison made between surgical limbs, healthy limbs and two types of braces suggested that the Lenox Hill derotation brace was exerting a form of rotatory control. Objectively the brace was found to reduce internal rotation and torque parameters. Similar results for another orthosis were obtained by Coughlin, et al. (1987), who concluded that the greatest effect of the Hangers A.C brace was an average decrease of internal rotation by 46% and 29% for external rotation. However this brace also failed to significantly decrease anterior tibial displacement. Beck, et al., (1986), reported the evaluation of four custom fit functional knee braces and it was concluded that while some were more effective in controlling anterior tibial displacement in the ACL deficient knee than others, none of the braces produced significant differences. Hofmann, et al., (1984) recognized one brace, the 3D 3-way orthosis, out of six commercially available knee orthoses as providing stability for anterior displacement and rotatory laxity. However again none of these results were verified statistically. Furthermore, the results may have been affected by the fact the testing was not performed on live subjects but rather on cadaver knee specimens.

Marquette (1988) reported that the orthosis should incorporate in its design two important features. First, the orthosis should effectively transfer force from the tibia to the femur in order to provide knee stability when it is necessary to compensate for a ruptured or deficient ligament. Essentially there are two types of external knee joints designed to accomplish this task. There is a fixed type axis and a polycentric linkage axis. The former defines rotation around a single axis while the latter provides for the rollback of the femur relative to the tibia during flexion. Depending on where the axis of either design is placed, in the sagittal plane, it can cause condylar impingement, condylar separation or excessive rollback during flexion (Walker, et al., 1985). The designers of the "2191" stabilizing knee orthosis implemented a single axis joint with a center 5/8" posterior of the anatomical center of the knee joint. The positioning was chosen so the slipping movement between the femur and the tibia would be minimized, keeping the femur and the tibia together. Consequently, it was thought that if the slipping motion was reduced then rotation would stop and the knee joint would be protected from further damage to the anterior cruciate and medial-lateral collateral ligaments. It should be noted that both designs are more simplified than the actual anatomical motion of the knee.

The second important feature that the orthosis should replicate is the exact anatomical motion of the knee joint. However, since the external knee joint is more simplified than the natural knee motion it can generate unwanted constraint forces within the orthosis which obstruct the joint motion and ultimately cause discomfort at different suspension points (Lew, et al., 1978). Schafer, et al. (1988) designed a N.U.K.O knee joint implemented with an articular surface. The joint closely mimics the natural knee motion by allowing five of the six possible degrees of freedom within the tibiofemoral joint. Following the evaluation of the external device it was proposed that on the average the knee joint generated 76% less pistoning constraint forces and therefore caused much less discomfort than the other joint designs.

2.4.2 Dynamic Testing

The primary focus in the evaluation of an orthosis during an activity is to demonstrate how the knee brace restrains higher functional forces. Knutzen (1987) assessed ground reaction force data and knee joint movement parameters as a method of evaluating the knee brace effectiveness. The results of the study were consistent with the currently available literature detailing the orthosis to have reduced internal rotation of the knee joint by 31% during running. Moreover, the ground reaction force data provided results indicating the greatest effects of knee bracing occured during the impact phase of the support period where the impact forces were maximized and thus suggesting that the brace is creating a significant alteration to the knee joint kinematics.

Both static and dynamic testing methods are essential in the total description of an orthosis. However the orthoses' ability to restrain movement caused by the insufficient integrity of the ligament should be tested prior to the involvement of the surrounding muscles of the knee joint. The reason being if the brace is not effective while the knee joint is maintained in a static position, it will certainly not provide the functional stability necessary during an activity. Therefore, the following study will conduct the initial phase of the analysis which is to evaluate an orthosis by a static testing method only.

CHAPTER III

METHODS AND PROCEDURES

Few studies have evaluated the efficacy of functional knee braces, particularly their ability to stabilize ACL deficient knees. The effectiveness of knee orthoses remains to be correctly quantified (Beck, 1986). Consequently, it is essential to evaluate objectively and quantitatively the efficacy of functional knee braces in stabilizing the translational and rotational components characteristic of an ACL deficiency. The results of such an evaluation would provide orthotic manufacterors with valuable information regarding the design of the orthosis. Furthermore, the results would assist orthopedic surgeons in accurately prescribing an orthosis of optimal efficiency.

The following procedures in this investigation were specifically chosen in order to objectively evaluate the ability of three functional knee orthoses in controlling the translational and rotational instabilities associated with an ACL deficiency. These instabilities are characterized as: (1) anterior laxity, (2) anterior midrange stiffness, (3) anterior endrange stiffness, (4) internal rotatory laxity, (5) internal midrange stiffness, (6) internal endrange stiffness, and (7) anterior translation of the lateral tibial plateau during internal rotation.

3.1 Subjects

This study comprised of a total of fifteen male and female subjects with known isolated anterior cruciate ligament deficiencies. The ACL injury was identified using two procedures. First a clinical exam was performed by an orthopedic surgeon. All subjects were evaluated as having a positive drawer sign of grade 2 or greater. The clinical grading scale was based on a classification system described by Houston (1976) and documented as follows:

- Grade 1+ Mild instability; tibiofemoral joint surfaces separate 5mm or less
- Grade 2+ Moderate instability; tibiofemoral joint surfaces separate between 10-15mm.
- Grade 3+ Severe instabilty; tibiofemoral joint surfaces separate more than 15mm.

Secondly, arthroscopic surgery was performed on all subjects to confirm the clinical diagnosis. Because this study focused on evaluating the efficiency of functional knee braces in controlling isolated ACL deficiencies, the subjects had no previous history of reconstructive surgery other than the diagnostic arthroscopy. Subjects were recently injured between six and twenty four months, to avoid degenerative bone changes. The data was obtained from the clinical records of the patients.

3.2 Testing Apparatus

The data for each subject was obtained using the Genucom

Knee Analyzer. The apparatus consists of a two drive computer based system located beneath a reclining seat. The computer system was controlled by a program disk designed by the manufacturers of the testing apparatus. A second disk was necessary to record the patient information and stability test results. The Genucom was designed with an electrogoniometer linkage which measures, three dimensionally, the displacement of the tibia relative to the femur. Specifically, axial rotations, translations, and flexion angles are recorded and can be viewed on a monitor by the technician employing the device. The Genucom is also equipped with six force transducers which are contained within a dynamometer and are built into the seat of the apparatus. The tranducers measure: (1) forces applied along the anterior/posterior, medial/lateral and compression/distraction axis and (2) rotational moments applied about the flexion/extension, varus/valgus, and internal/external axis.

The Genucom software is programmed to obtain displacement values as a function of force and/or moments applied to the tibia. Both force (moment) and displacement data are time dependent and the number of readings taken per second can be adjusted. For this particular study the frequency was set at 15 Hz.

A unique feature of the Genucom Knee Analyser is its ability to account for femoral movement elicited during the test. The apparatus accomplishes this with a soft tissue compensation procedure which accounts for the effect of distal femoral displacement within the surrounding tissue. During the soft tissue compensation procedure, specific translational and rotational loads were applied at the distal femur and corresponded to the axis in which the tibial loads were applied during the stability tests. The result of the applied load was a soft tissue force/displacement curve. Since the characteristics of soft tissue are different for each subject, due to the different ratios between adipose and muscle tissue, the relative displacement of the femur was subject specific. This specificity meant that no normative soft tissue curve existed for comparison. As a result, the soft tissue compensation had to be done twice, after which the two generated curves were compared to verify the validity of the measurement. The comparison was between each displacement measure corresponding to a specific force value for both compensation curves. The Genucom program statistically calculated the number of displacement measures obtained between the two soft tissue compensation curves that differed by less than two millimeters and then reported it as a percentage. A high percentage indicated a high correlation between the two compensation curves while a low percentage indicated that a greater number of displacement values between the two curves differed by more than two millimeters. The manufacterors of the device recommend that a soft tissue value of 85% or more should be obtained in each axis when performing the compensation procedure. Once the soft tissue compensation was completed, the soft tissue displacement values were subtracted from the displacement values obtained during a stability test, thus effectively removing the motion of the femur due to the compliant characteristics of soft tissue. This feature is unique in that other testing devices such as the KT 1000 and Styker do not account for femoral movement within the thigh.

3.3 Description of Study

This investigation assessed three functional knee braces and involved fifteen subjects as follows: (1) 5 fitted with brace 1, (2) 5 fitted with brace 2 and (3) 5 fitted with brace 3.

3.4 Testing Protocol

The Genucom Knee Analyzer was developped by Far Orthopedics Inc (Figure 6). The testing protocol was designed to evaluate the injured and uninjured knee joints without an orthosis. Some modifications had to be made to the testing protocol in order to accomadate an orthosis. Hence the modified testing protocol was designed as follows:

Patient Installation

The subject was installed into the device with a hip and knee flexion of approximately 15° and 90°, respectively. The hips were stabilized with two lateral pads and a strap placed around the abdomen stabilized the pelvis. The subject was seated in the Genucom so that the knee extended beyond the edge of the seat by at least two inches (this was verified by ensuring that two fingers could fit between the posterior aspect of the upper lower leg and the edge of the seat). The lateral side of the thigh was aligned with the lateral edge of the seat. In order to test the effect of the orthosis on the injured knee only the leg was in direct contact with the seat of the genucom and not the orthosis. This was accomplished by placing a padded block beneath the upper thigh in such a manner that it did not touch the brace.

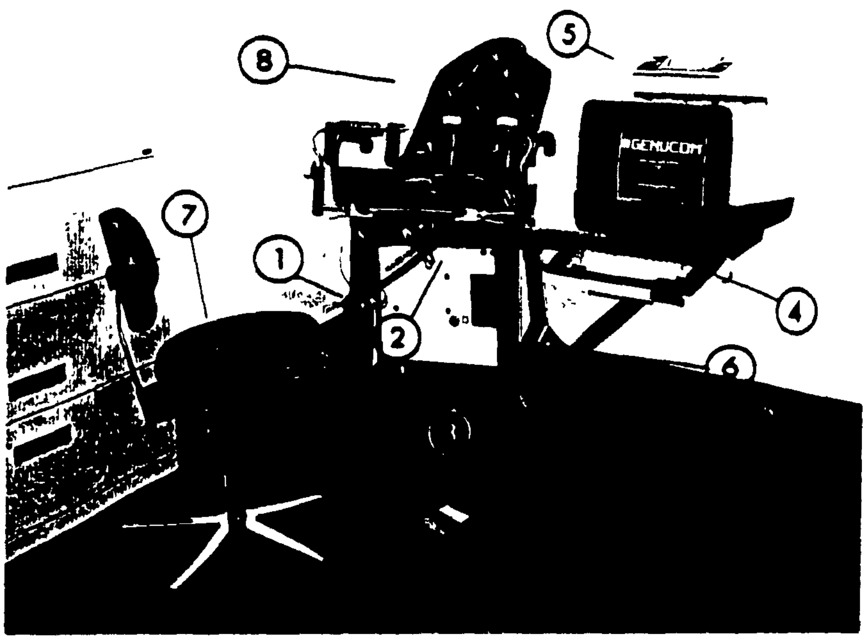


Figure 6. Illustration of the Genucom Knee Analyzer.
(1) Six component electrogoniometer and digitizer
(2) Six component dynamometer
(3) Computer with Dual Disk Drives
(4) Monitor and keyboard
(5) Printer
(6) Monitor support
(7) Examiner's chair
(8) Reclining examination chair

Restraining the Thighs

Three thigh restraints were placed medially, laterally, and horizontally to the femur. This procedure was done by resting three rods on three pads which layed on the surface of the skin. The rods and pads were not placed on any aspect of the brace, patella or tibia. However the pads could be adjusted to lay under the medial or lateral support bars of the brace. As the thigh restraints were placed the Genucom monitored the actual clamping forces to the femur. The medial and lateral restraints were placed first at a force of approximately 32 lbs and the horizontal restraint at a force of 25lbs.

Both of the above procedures, Patient Installation and Restraining the Thighs, were performed to prevent femoral movement from occuring within the surrounding soft tissue.

ATTACHING THE TIBIA SUPPORT

A three dimensional electrogoniometer which measures displacement and flexion angles between the tibia and femur was mounted onto the tibial support at the lower leg just above the malleoli. Two tibia supports were available, one for subjects whose height was 5'6" or less and a larger support for patients greater than 5'6". The tibial support was aligned with the tibial crest and secured by an elastic strap with velcro closures. This procedure was not affected by an orthosis and is the same as the protocol outlined in the Genucom manual.

Digitizing the Anatomical References

The exact geometry and location of each knee with respect to the Genucom base was provided by digitizing specific points in three dimensional space. Seven digitized points provided a reference location from which flexion angles and the center of the knee were measured. The seven digitized points were the following:

1. Tibial crest 6-8 inches below the proximal end.
2. Tibial crest 2-3 inches below the proximal end. This landmark was covered by the tibial shell of the knee brace and therefore the digitized point was taken in line with the tibial crest in order to resemble the actual anatomical site.
3. The tibial tubercle was also covered by the brace. Therefore digitization of this point was done such that it was in line with the tibial crest and just below the patella.
4. The medial and lateral edge of the proximal tibia was at times covered by the medial and lateral aspect of the tibial shell. However if the knee was flexed at 90° the orthosis shifted anteriorly and made it possible to locate and digitize the medial and lateral joint lines.
5. The top of the medial and lateral femoral condyles were not obstructed by the brace and were digitized in the usual manner.

The center of the knee was calculated for purposes of describing displacement between the tibia and femur when forces were applied to the knee joint. The Genucom software provided the necessary calculations and were described as follows:

(a) The center of the knee in the medial/lateral axis was defined as the bisector between the medial and lateral points of the last four areas digitized.

(b) The center of the knee in the tibial axis was defined by a point 3/4 of the way between the two points measured on the tibial plateaus and femoryle condyles.

(c) Finally the center of the knee in the ant/post direction was defined as the average of the ant/post position of the two points, measured at the medial and lateral side of the proximal tibia.

The center of the medial and lateral plateaus were calculated as being one centimeter from the center of the knee in the medial/lateral axis. This calculation was performed to describe the anterior translation of the tibial plateaus.

Soft Tissue Compensation Procedure

The technique that was employed when performing the soft tissue compenstion for a knee with an orthosis was the same as the protocol for a knee without an orthosis except that extra caution was taken. For example the forces were applied directly on the surface of the skin and not through the brace. Femoral motions were measured in the following three directions.

1) Medial/Lateral Translation: A force of 130N was applied with the palm of the hand to the boney prominence of the distal femoral condyles first in the medial direction then in the lateral direction.

2) Anterior/Posterior Translation: The posterior translation of the femur was measured at a force of 130N applied posteriorly on the top of the distal femoral condyles towards the ankle. The anterior translation was measured by applying an anterior force to the heel of the foot and lifting the leg in an effort to displace the proximal end of the femur anteriorly. The knee joint was maintained at an 90° angle for both anterior and posterior measurements.

3) Proximal Translation: A force of 130N was applied to the patella in the direction of the femoral axis.

Each force application was performed twice for approximately three seconds. It was important that each application was performed smoothly without jerky movements for the two curves to highly correlate.

Protocol for Establishing Criterion Variables

The criterion variables were derived from two types of stability tests, anterior\posterior drawer test and internal\external stress test. The testing procedure was performed as cautiously as the soft tissue compensation procedure and all loads were applied to the surface of the skin and not the orthosis.

The Anterior/Posterior drawer test was performed with an applied force of 135N in both the anterior and posterior directions at 20°, 30°, 40° and 90° knee flexion. As previously described, studies done by Lew (1982), France (1983), and Ahmed (1987) used a buckle transducer to obtain ligament tensions and found that the ACL produced the greatest tension between 0° and 40° and at 90° of flexion. Thus flexion angles of 20°, 30°, 40°, and 90° were chosen to best reflect the integrity of the ACL.

The Anterior/Posterior drawer test generated a force-displacement curve from which both laxity and stiffness values were derived. Anterior laxity (ALAX) for all four flexion angles was obtained at a force value of 125N. Functionally forces ranging from 100N to 150N do not replicate the magnitude of actual translational forces which can range from 300N to 500N during activity. However functional forces applied to a knee joint in a static position could cause structural damage to the passive restraining structures. Therefore as a precautionary measure a clinical load was applied to the knee joint. Ideally a greater clinical load of approximately 200N should have been applied (Markolf, 1987 and Beck, 1986). However, due to the physical limitations of the technician and the associated discomfort to the subject, a force value of 125N was chosen as an appropriate load for both the subject and technician. Anterior midrange stiffness (AMRS) was quantified by computing the inverse slope of the force-displacement curve between force values of 30N and 70N. Anterior endrange stiffness (AERS) was evaluated between forces values of 120N and 130N. As defined in the literature it is not clear which stiffness value best describes the integrity of the ACL. Thus both stiffness parameters were evaluated in this study.

The Internal/External stress test was performed with an applied torque of 9Nm in both the internal and external directions at 90° flexion. From the resulting torque-displacement curve, internal rotatory laxity (ILAX) was computed at a torque value of 8Nm. Several invitro studies have evaluated rotatory laxity at a variety of torque values (Lipke, 1981; Ahmed, 1987; and Markolf, 1976). Fewer invivo studies have been performed evaluating rotatory instabilities. Markolf (1984), determined int/ext laxity values at a torque of 10NM. Since very little literature has identified invivo rotatory laxity values, the parameters chosen for this study were relatively new.

Along with laxity parameters the Internal/External stress test generated data detailing the anterior translation of the lateral tibial plateau during internal rotation (TLTP). This translation was measured at an internal rotatory value of 15°. The literature supports this parameter however translation of the tibial plateaus was measured as a function of torque. The genucom software does not provide this measurement as a function of torque and instead was calculated as a function of displacement (degrees).

Both anterior/posterior drawer tests and internal/external stress tests require an established neutral point in which all knees should be positioned prior to testing. Unfortunately there was little agreement within the literature regarding the clinical significance of establishing a "neutral zone". This in part was due to the difficulty of defining this parameter in quantitative terms. Butler (1980) defined the neutral position of the knee as the point along a force-displacement curve where stiffness was smallest. Fukubayashi (1982) defined this parameter in a similar manner and determined the neutral point to be the area between anterior and posterior inflection points on a force displacement curve. Mueller (1985) defined the neutral position of the knee somewhat differently and considered the tibia and femur to be aligned neutrally in an anatomic standing position. However he also stated that the detection of a neutral point between ant/post and ext/int displacements is extremely difficult if not impossible to determine. Thus taking this into consideration the neutral point was determined as the position in which the tibia and femur are aligned when the knee is flexed at 90° and no external load is applied to the tibia (Far Orthopedics, 1984).

3.5 Experimental Design

The experimental design was divided into three parts. The first part investigated whether each brace was providing a constraint to inhibit translational instabilities. The second part investigated the differences between the three braces in maintaining translational stability. The third part of the design investigated the differences between the three braces in maintaining rotatory stability.

3.5.1 PART 1

Three, one-factor ANOVAs were used to define the translational characteristics: (1) ALAX, (2) AMRS, and (3) AERS. Factor A included the four levels of flexion angle; 20°, 30°, 40° and 90°. Factor B detailed one level of knee condition.

Factor B: Knee Condition	Factor A: Flexion Angle 20°	30°	40°	90°
BRACE EFFECT				

3.5.2 PART 2

Three, two-factor ANOVAs were used to define the translational characteristics: (1) ALAX, (2) AMRS, and (3) AERS. Factor A included four levels of flexion angle; 20°, 30°, 40°, and 90°. Factor B included three brace types; brace 1, brace 2 and brace 3.

Factor B: Brace Type	Factor A: Flexion Angle 20°	30°	40°	90°
Brace 1				
Brace 2				
Brace 3				

3.5.3 PART 3

Two, one-factor ANOVAs were used to define the remaining rotational characteristics: ILAX and TLTP. Factor A included of the type of brace condition; brace 1, brace 2, and brace 3. Factor B included the one level of flexion angle; 90°.

	Factor A: Brace Type		
	Brace 1	Brace 2	Brace 3
Factor B: Flexion Angle 90°			

CHAPTER IV

ANALYSIS AND RESULTS

The purpose of this study was twofold. First, to objectively evaluate the differences in stiffness and laxity profiles throughout a range of motion for three functional knee braces. Second, to investigate the general differences between the three braces. The results of the proposed objectives are presented within this chapter. This chapter includes the following sections: 1. subject description and pathological history, 2. subject inclusion parameters, 3. a comparison of translational laxity and stiffness parameters between injured knees and injured knees fitted with a brace, across four flexion angles, 4. a comparison among the three knee braces for translational laxity and stiffness values and 5. a comparison among the three knee braces for rotational laxity and stiffness values.

4.1 SUBJECT DESCRIPTION

This study consisted of a randomized block design where five subjects were fitted with brace 1, five subjects were fitted with brace 2 and five subjects were fitted with brace 3. A total of fifteen subjects were assessed in this investigation. All fifteen subjects were referred by physicians and brace manufacturers. The subjects were described as having demonstrated a unilateral anterior cruciate deficiency. However, a revision of patient information forms revealed that all subjects did not contain isolated injuries.

The subject sample consisted of ten anterior cruciate deficient knees, three anterior cruciate deficient knees with associated medial collateral injuries and two anterior cruciate deficient knees with associated medial collateral injuries and medial meniscal lesions. The average subject age was twenty-eight (± 5 years). The length of time post injury ranged from three months to three years. A majority of the injuries were diagnosed by arthroscopic surgery, in all a total of thirteen subjects had undergone the diagnostic surgery. The remainder were assessed clinically. The information collected from the patient information forms is summarized in Table 1.

TABLE 1

SUBJECT INFORMATION

SUBJECT	AGE	DATE OF INJURY	DATE OF ARTHROSCOPY	TYPE OF INJURY	BRACE TYPE
1.	20	Jan. 1988	Sept. 1988	ACL	Brace1
2.	24	May 1986	Feb. 1987	ACL	Brace1
3.	34	Jan. 1986	Oct. 1988	ACL	Brace1
4.	22	Jan. 1988	June 1988	ACL	Brace1
5.	35	July 1986	Feb. 1986	ACL	Brace1
6.	21	June 1988	Nov. 1988	ACL & MCL & med.mensc.	Brace2
7.	40	Oct. 1987	Mar. 1988	ACL	Brace2
8.	23	Dec. 1987	---------	ACL	Brace2
9.	22	Feb. 1987	Aug. 1988	ACL	Brace2
10.	26	Mar. 1989	May 1989	ACL & MCL & med. mensc.	Brace2
11.	35	Sept.1986	Feb. 1987	ACL & MCL	Brace3
12.	25	May 1986	Apr. 1987	ACL & MCL	Brace3
13.	36	Jan. 1988	June 1988	ACL	Brace3
14.	28	Oct. 1988	Feb. 1989	ACL & MCL	Brace3
15.	29	Mar. 1989	---------	ACL	Brace3

4.2 SUBJECT INCLUSION PARAMETERS

The data collected in Table 1 reveals that the subject sample contained knee pathologies which were not the result of an isolated ACL rupture. Thus, a second procedure was used to further verify which subjects had abnormal knee pathologies characteristic of an ACL injury. This analysis involved measurement of right knee-left knee laxity differences at 20° flexion. The results of this analysis are summarized in Table 2.

TABLE 2

RIGHT KNEE-LEFT KNEE ANTERIOR LAXITY DIFFERENCES

Brace type	Subjects	20°
1	1.	3.37
1	2.	4.43
1	3.	2.74
1	4.	13.23
1	5.	6.20
2	6.	8.40
2	7.	5.44
2	8.	-3.10
2	9.	3.00
2	10.	1.60
3	11.	5.47
3	12.	3.60
3	13.	10.63
3	14.	0.60
3	15.	-0.62

The right knee-left knee laxity differences was a procedure employed by Daniel et al., (1985). The results identify the deficiency as a relative quantity. The study assumed bilateral symmetry and a unilateral injury. Daniel categorized the differences into three conditions; 1. normal anterior laxity: defined as the displacement difference of 1.5 mm or less, 2. equivocal anterior laxity: defined as a displacement difference ranging from 2 to 2.5 mm and 3. abnormal anterior laxity: defined as the displacement difference of 3 mm or greater. The study graded anterior laxity differences in slight flexion (between 0°-20°). Table 3 contains a modified version of Daniel's categories and served as subject inclusion parameters for this particular study.

TABLE 3

MODIFIED CATEGORIES CHARACTERIZING

ANTERIOR LAXITY DIFFERENCES AT 20° FLEXION

1. NORMAL ANTERIOR LAXITY:	$\leq$ 1.0mm
2. EQUIVOCAL ANTERIOR LAXITY:	between 1mm and 3mm
3. ABNORMAL ANTERIOR LAXITY:	> 3mm

The new sample population consisted of a total of eleven subjects. The decision to omit the results of four subjects with normal knee laxity was further supported by comments written by three of the subjects, indicating that on several occasions during the testing they experienced mild pain. This discomfort in all probability caused the subjects to contract their hamstrings and quadriceps isometrically, causing an increase strain within the joint and potentially increasing the limitations of the study.

4.3 A COMPARISON OF LAXITY AND STIFFNESS PARAMETERS BETWEEN INJURED KNEES AND INJURED KNEES FITTED WITH THREE DIFFERENT BRACES AT FOUR FLEXION ANGLES.

The first analyses focused on two aspects. First, how effectively each orthoses compensated for the lacking stiffness parameters and second, how efficiently each orthoses controlled anterior translation. Sections 4.3.1, 4.3.2, and 4.3.3 detail the descriptive statistics, ANOVA results and mean comparisons for subject groups fitted with brace 1, brace 2 and brace 3, respectively.

All of the proceeding analyses investigate the effect of three braces, however, three separate subject groups were fitted with a different type of brace. As a means of comparing the three groups, the contralateral uninjured knee was considered a control group. Therefore all translational and rotational stiffness and laxity profiles are described as differences between the intact knee and injured knee fitted with and without a brace.

4.3.1 DESCRIPTIVE STATISTICS AND ANOVA RESULTS FOR BRACE 1

Table 4 details the descriptive statistics for the stiffness and laxity profiles of brace 1. The first column in Table 4 describes the mean differences between injured knees and contralateral intact knees at four flexion angles. This measurement described the deficiency throughout a range of motion. The second column demonstrated the mean differences between injured knees fitted with brace 1 and contralateral intact knees at four flexion angles. Thı. measurement indicated the effect of brace 1 on the deficiency. Finally, the last column provided the mean differences between injured knees and injured knees fitted with brace 1. This value represented the amount of stability provided by the brace. Figures 7, 8 and 9 depict the percent differences between the brace effect and the deficiency throughout a range of motion, for anterior midrange stiffness (AMRS), anterior endrange stiffness (AERS) and anterior laxity (ALAX), respectively.

In general, Figure 7 illustrates that brace 1 decreased the mean AMRS differences throughout the four flexion angles. Brace 1 appears to produce the greatest differences at 90° and 20° flexion and are identified by percent differences of -25% and -13.9%, respectively. A one way ANOVA was conducted to further verify whether the differences in brace effect were significantly different across the four flexion angles. The F ratio of 0.25 in column three of Table 4 reveals no significant differences for AMRS (alpha=0.05).

Figure 8 demonstrates that brace 1 had a varying effect on AERS. Brace 1 decreased the mean AERS differences at 40° and 20° flexion, whereas it increased the differences at 90° and 30° flexion. The percent differences of +107% and +155% imply that the involved knee without brace 1 produced greater stiffness than when fitted with brace 1. A one way ANOVA failed to reveal any significant differences across flexion angles (F ratio= 0.4700).

The mean ALAX differences shown in Figure 9 illustrate the effectiveness of brace 1 in decreasing anterior laxity throughout the range of motion. The greatest effect of brace 1 appeared at 20° flexion, which was characterized by a 70% decrease. Furthermore, the restaint provided by brace 1 was consistent at 90°, 40°, and 30°.

TABLE 4

DESCRIPTIVE STATISTICS OF BRACE 1

	DEFICIENCY (Involved-Intact)	BRACE EFFECT (Brace-Intact)	STABILITY (Involved-Brace)
	$\bar{X} \pm$ S.D N=5	$\bar{X} \pm$ S.D N=5	$\bar{X} \pm$ S.D N=5
AMRS (N/MM)			
90°	-38.70 ± 33.52	-28.96 ± 21.05	-9.74 ± 21.23
40°	-36.62 ± 23.58	-36.02 ± 22.36	-0.60 ± 2.03
30°	-56.12 ± 28.10	-53.53 ± 25.29	-2.63 ± 3.96
20°	-72.26 ± 28.99	-62.65 ± 23.87	-10.01 ± 9.78
AERS (N/MM)			
90°	-5.49 ± 30.15	-11.39 ± 16.89	5.90 ± 20.72
40°	-14.30 ± 13.83	-10.99 ± 13.54	-3.31 ± 12.13
30°	-4.60 ± 26.31	-11.74 ± 18.76	7.14 ± 25.82
20°	-14.73 ± 18.44	- 3.58 ± 10.46	-11.15 ± 22.84
ALAX (MM)			
90°	5.64 ± 3.20	3.28 ± 4.65	2.36 ± 2.60
40°	11.88 ± 2.04	7.66 ± 5.82	4.22 ± 4.65
30°	11.71 ± 3.73	8.31 ± 6.08	3.40 ± 6.45
20°	8.60 ± 2.33	2.61 ± 2.32	5.99 ± 4.25

Overall, the values presented in Table 4 demonstrate that

Figure 7

Mean Anterior Mid-Range Stiffness
Differences for Brace 1

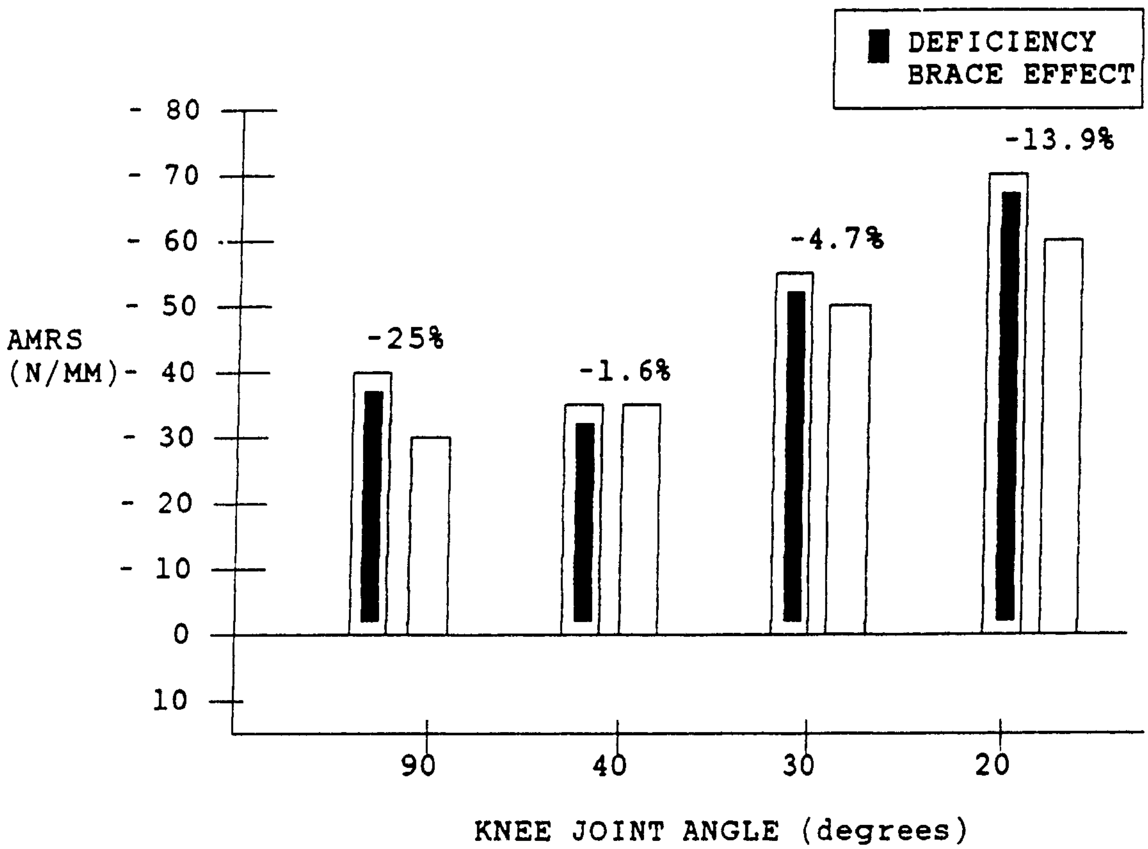


Figure 8

Mean Anterior End-Range Stiffness
Differences for Brace 1

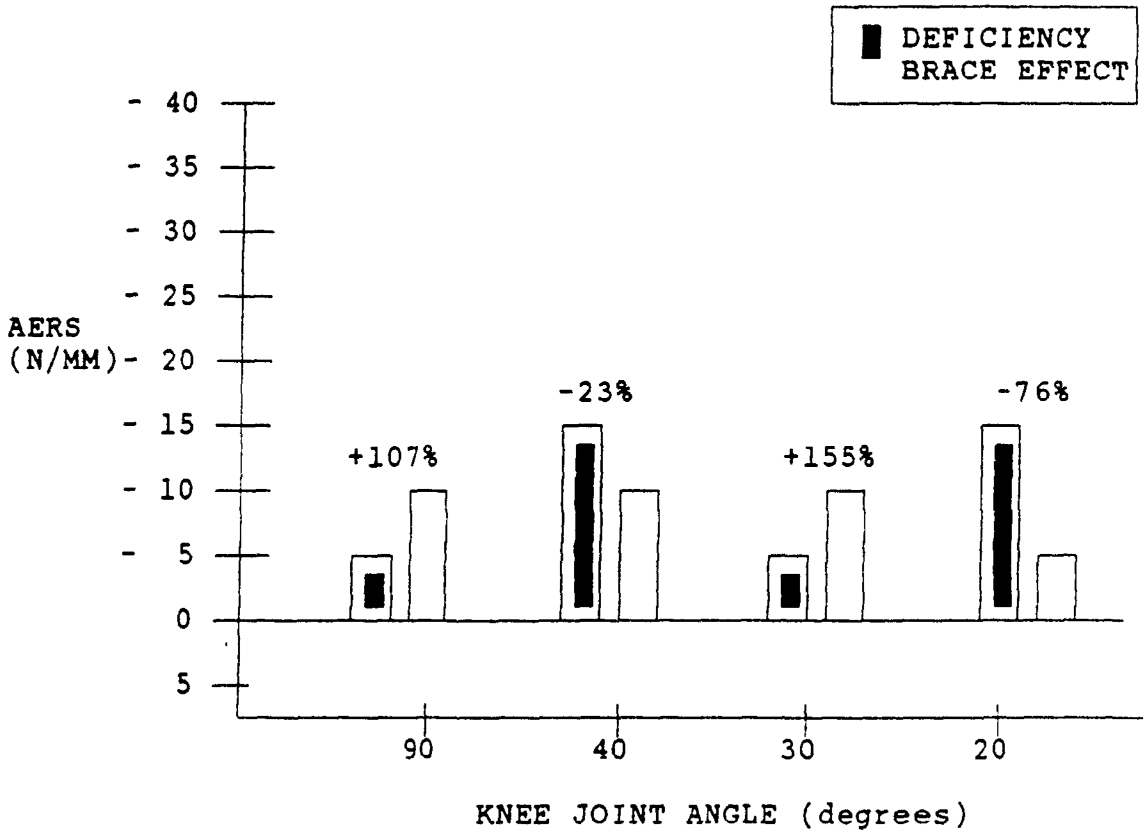
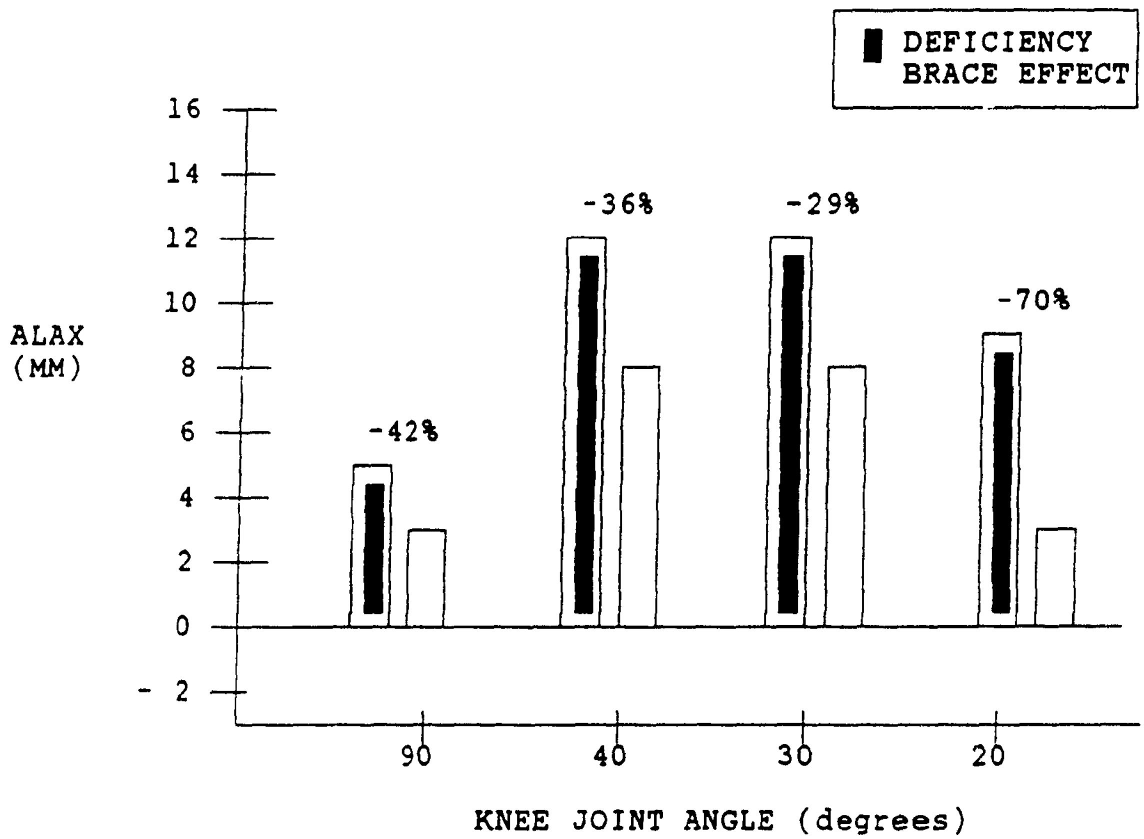


Figure 9

Mean Anterior Laxity
Differences for Brace 1



first, brace 1 is restraining anterior laxity, particularly at 20°. Second, the effect of brace 1 on the two stiffness profiles is different. The AMRS stability differences were consistent, whereas the AERS values were characterized by large fluctuations. Finally, the laxity profile demonstrated that the deficiency was most apparent at 40° and 30° flexion.

4.3.2 **DESCRIPTIVE STATISTICS AND ANOVA RESULTS FOR BRACE 2**

The descriptive statistics presented in Table 5 describe the stiffness and laxity profiles of brace 2.

Figure 10 demonstrates the effect of brace 2 on mean AMRS differences. Generally, the brace decreased the differences throughout the range of motion. However, it is important to observe that the injured knees fitted with brace 2 provided a greater amount of stiffness than the contraleral intact knees, at 40° and 20° flexion. This is characterized by differences of -184% and -188%. A one way ANOVA further verified that the differences in stability were not significant across flexion angles (F= 0.57) indicating no significance.

Similar to the AMRS results, brace 2 decreased the AERS deficiency across all four flexion angles. Furthermore, the injured knees fitted with brace 2 provided a greater restraint than the intact knees, at 40° and 20° flexion. There were no significant differences across flexion angles (F ratio=0.83).

Figure 12 reveals that brace 2 decreased the mean ALAX deficiency differences throughout the range of motion. Furthermore, at 90° and 20° flexion, the injured knees fitted with brace 2 appeared to reduce laxity to a greater extent than the intact knees. Once again, a one way ANOVA revealed no significant differences across flexion angles (F ratio=0.06).

TABLE 5

DESCRIPTIVE STATISTICS OF BRACE 2

	DEFICIENCY (Involved-Intact)	BRACE EFFECT (Brace-Intact)	STABILITY (Involved-Brace)
	$\bar{X}$ ± S.D N=3	$\bar{X}$ ± S.D N=3	$\bar{X}$ ± S.D N=3
AMRS (N/MM)			
90°	-4.29 ± 6.11	1.35 ± 4.32	-2.94 ± 6.89
40°	-2.70 ± 3.38	-2.26 ± 3.09	-4.96 ± 6.87
30°	-7.71 ± 11.59	4.01 ± 2.16	-3.70 ± 4.15
20°	1.52 ± 0.51	-1.34 ± 0.98	-2.86 ± 7.21
AERS (N/MM)			
90°	5.55 ± 26.23	-7.24 ± 20.12	-1.69 ± 36.84
40°	-1.51 ± 1.79	-23.27 ± 23.07	-24.78 ± 28.99
30°	10.65 ± 29.66	-4.26 ± 10.21	-6.39 ± 9.06
20°	-4.73 ± 16.99	-10.97 ± 19.74	-15.70 ± 20.34
ALAX (MM)			
90°	0.38 ± 2.91	1.31 ± 1.75	1.51 ± 1.89
40°	4.83 ± 0.99	-0.32 ± 0.59	4.51 ± 0.61
30°	6.33 ± 1.01	-1.26 ± 0.87	5.07 ± 1.78
20°	4.45 ± 2.94	1.16 ± 2.93	5.61 ± 2.43

In summary, the results presented in Table 5 indicate that first, brace 2 is restraining anterior laxity. Furthermore the deficiency and effect of brace 2 follow the same patterns as

Figure 10

Mean Anterior Mid-Range Stiffness
Differences for Brace 2

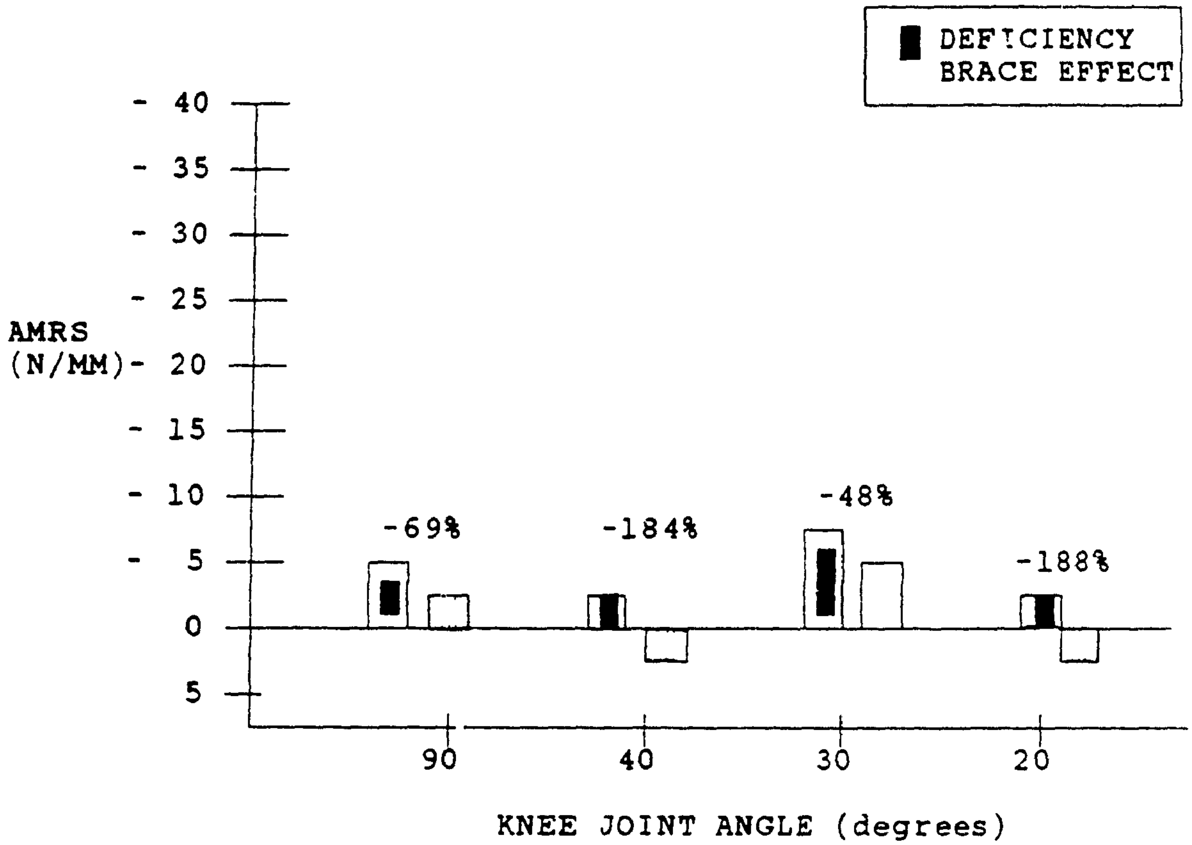


Figure 11

Mean Anterior End-Range Stiffness
Differences for Brace 2

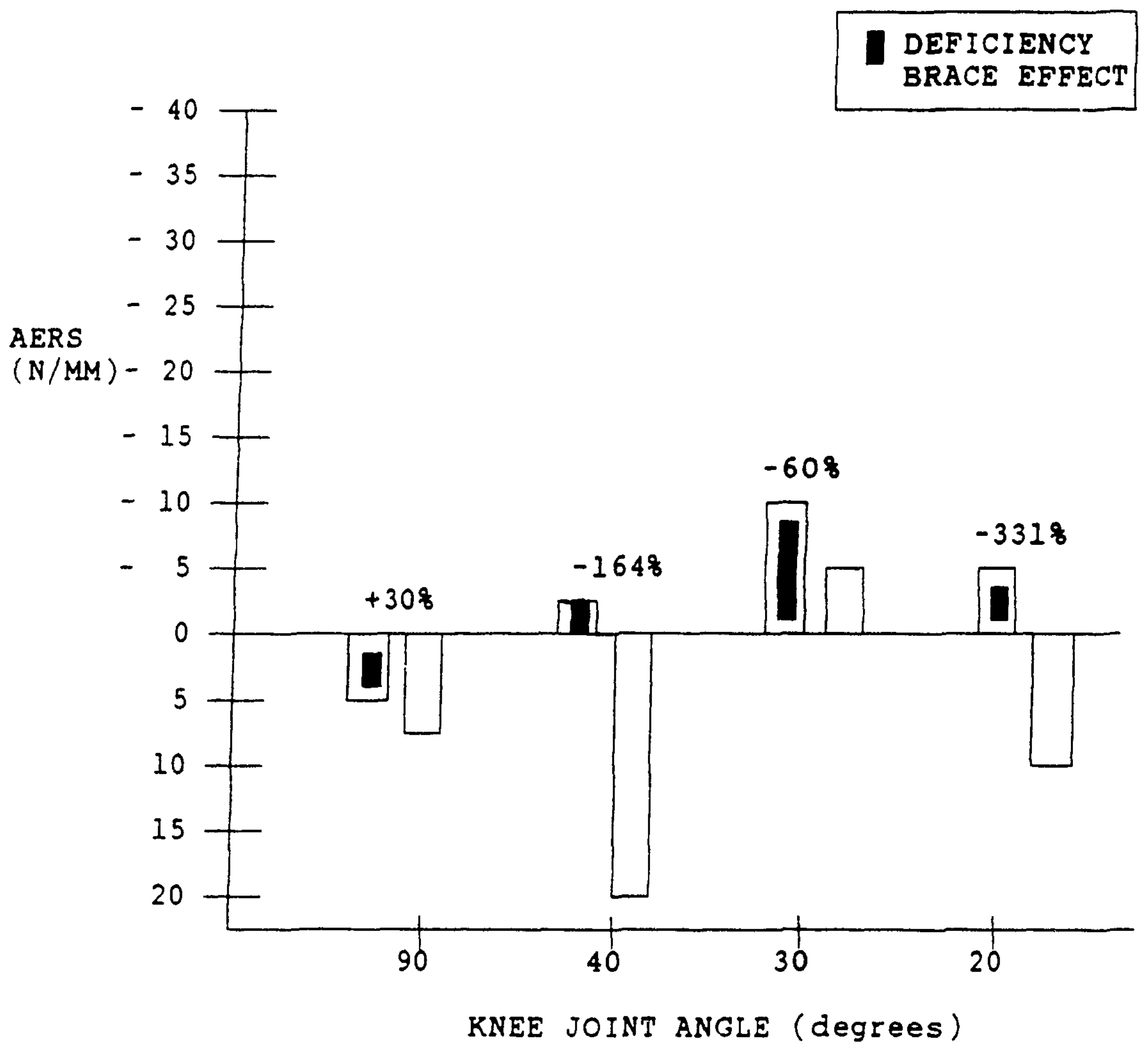
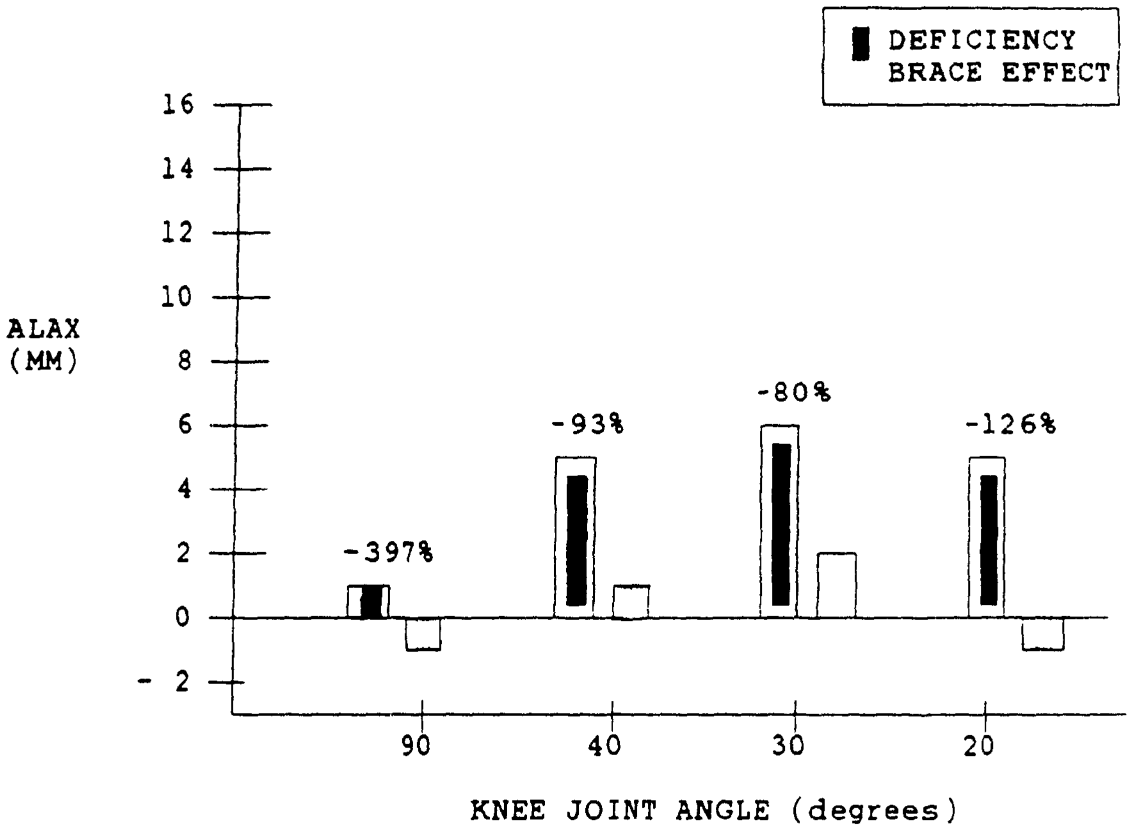


Figure 12

Mean Anterior Laxity
Differences for Brace 2



those demonstrated for brace 1. Second, the effect of brace 2 on the two stiffness profiles was similar. Specifically, at 40° and 20° flexion. In addition, the stiffness profiles showed inconsistent stability differences across flexion angles. Finally, the stiffness and laxity profiles of brace 2 imply that the greatest amount of anterior restraint is provided at 20° flexion.

4.3.3 <u>DESCRIPTIVE STATISTICS AND ANOVA RESULTS FOR BRACE 3</u>

The descriptive statistics presented in Table 6 reflect the stiffness and laxity profiles of brace 3.

Figure 13 demonstrates a general decrease in mean AMRS throughout the range of motion. However, the amount of stability provided by brace 3 is characterized by large fluctuations, particularly, at 20° and 30° flexion, where the injured knees fitted with brace 3 provide a greater restraint than the intact knees. No significant differences were obtained across the four flexion angles (F ratio=0.14).

The deficiency values provided in Table 6, for AERS, indicate that the involved knee provided a greater stiffness profile than the intact knee. Furthermore, the stability provided by brace 3 was characterized by large fluctuations across the four angles. A F ratio of 0.40 revealed no significant differences among the stability values.

In general, Figure 15 demonstrated that brace 3 decreased the amount of laxity across all flexion angles. Flexion angles of 40°, 30° and 20° were most affected, with the braced knees providing greater restraint than the intact knees. A one way ANOVA across the four flexion angles revealed no significant differences (F ratio=0.89).

TABLE 6

DESCRIPTIVE STATISTICS OF BRACE 3

	DEFICIENCY (Involved-Intact)	BRACE EFFECT (Brace-Intact)	STABILITY (Involved-Brace)
	$\bar{X}$ ± S.D N=3	$\bar{X}$ ± S.D N=3	$\bar{X}$ ± S.D N=3
AMRS (N/MM)			
90°	-23.16 ± 31.82	10.13 ± 20.26	-13.03 ± 21.07
40°	-3.52 ± 2.09	0.29 ± 1.13	-3.23 ± 1.71
30°	-3.86 ± 4.36	-1.76 ± 3.59	-5.62 ± 4.25
20°	-5.49 ± 8.74	-35.53 ± 10.95	-41.02 ± 14.79
AERS (N/MM)			
90°	-0.63 ± 4.61	-5.81 ± 8.34	-6.44 ± 12.83
40°	4.02 ± 2.11	-4.04 ± 4.38	-0.02 ± 7.28
30°	4.55 ± 1.68	-2.47 ± 3.31	2.08 ± 7.90
20°	9.84 ± 11.96	-31.83 ± 24.75	-21.99 ± 29.19
ALAX (MM)			
90°	4.79 ± 2.29	-0.86 ± 2.79	3.93 ± 3.56
40°	2.04 ± 2.49	2.01 ± 1.73	4.05 ± 2.16
30°	1.98 ± 1.24	3.01 ± 1.02	4.99 ± 1.50
20°	2.94 ± 2.34	3.63 ± 1.96	6.57 ± 3.64

Overall, the results presented in Table 6 indicate the following: 1. brace 3 provides a restraint to anterior laxity, 2. the stiffness profiles of brace 3 were characterized by large

Figure 13

Mean Anterior Mid-Range Stiffness
Differences for Brace 3.

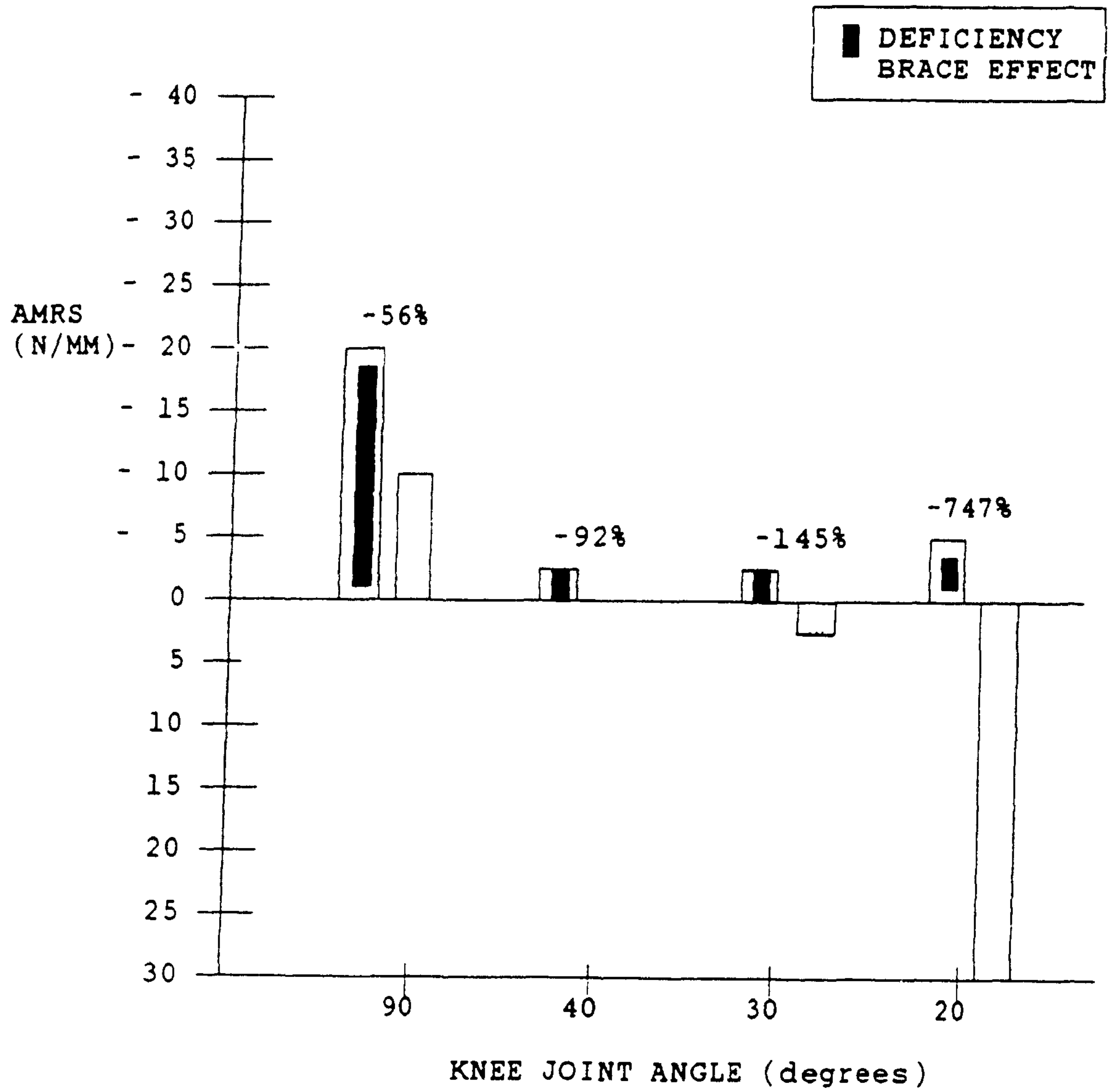


Figure 14

Mean Anterior End-Range Stiffness
Differences for Brace 3

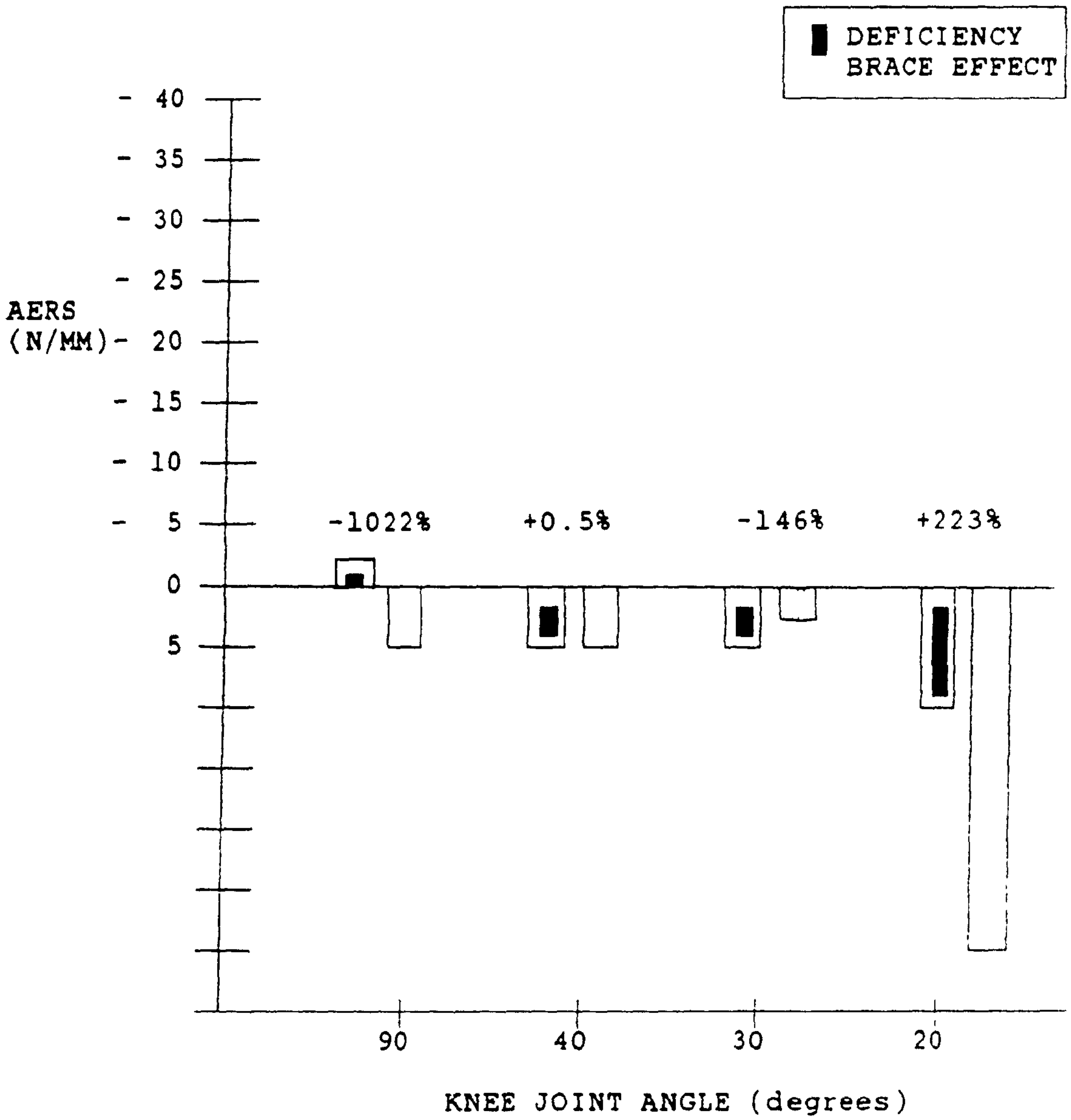
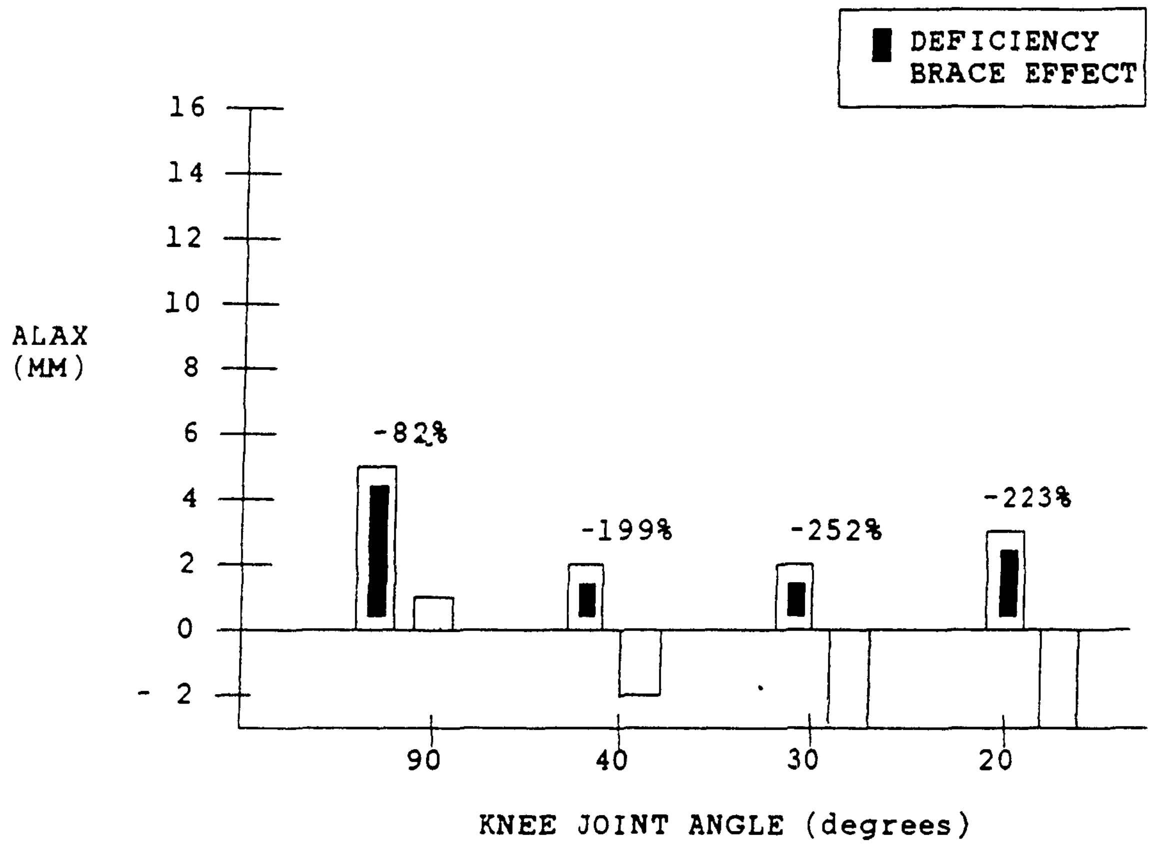


Figure 15

Mean Anterior Laxity
Differences for Brace 3



fluctuations in stability differences, 3. brace 3 restrained laxity to a greater degree than the intact knees and 4. the deficiency patterns in ALAX values were not similar to those demonstrated by the group of subjects fitted with brace 1 and brace 2.

4.4 A COMPARISON OF LAXITY AND STIFFNESS PROFILES AMONG THE THREE KNEE BRACES

The following sections focus on the comparison of stiffness and laxity parameters between brace 1, brace 2, and brace 3 at four flexion angles. Sections 4.4.1, 4.4.2, 4.4.3 detail the descriptive statistics, ANOVA results and mean comparisons for AMRS, AERS and ALAX, respectively.

4.4.1 Descriptive statistics, ANOVA results and mean comparisons for AMRS

Table 7 details the descriptive statistics for AMRS values across the three braces. The final column describes the F ratio obtained from a one way ANOVA across the three braces. The resulting F ratio of 0.005 at 20° flexion reveals significant differences across the three braces. A post hoc Tukey test was used to determine significance between the braces. The comparisons indicated that significant differences occured between: brace 1 and brace 3, also between brace 2 and brace 3.

Figure 16 illustrates that at 20° flexion the effect of brace 3 was greatest overall. It's effect was significantly larger than both brace 1 and brace 2.

TABLE 7

DESCRIPTIVE STATISTICS FOR AMRS, AERS and ALAX

STABILITY (Involved - Brace)				
	Brace 1	Brace 2	Brace 3	
Flexion Angle	X ± S.D N=5	X ± S.D N=3	X ± S.D N=3	F SIG
AMRS (N/MM)				
90°	-9.74 ± 21.23	-2.94 ± 6.89	-13.03 ± 21.07	0.80
40°	-0.60 ± 2.03	-4.96 ± 6.87	-3.23 ± 1.71	0.33
30°	-2.63 ± 3.96	-3.69 ± 4.15	-5.62 ± 4.25	0.62
20°	-10.00 ± 9.78	-2.86 ± 7.21	-41.02 ± 14.79	0.005
AERS (N/MM)				
90°	5.99 ± 20.72	-1.69 ± 36.85	-6.44 ± 12.83	0.78
40°	-3.31 ± 12.13	-24.78 ± 28.62	-0.02 ± 7.28	0.21
30°	7.14 ± 25.82	-6.39 ± 9.06	2.08 ± 7.90	0.65
20°	-11.15 ± 22.84	-15.70 ± 20.33	-21.99 ± 29.19	0.83
ALAX (MM)				
90°	2.36 ± 2.60	1.51 ± 1.90	3.93 ± 3.56	0.56
40°	[illegible].22 ± 4.65	4.51 ± 0.61	4.05 ± 2.16	0.99
30°	3.40 ± 6.46	5.07 ± 1.78	4.99 ± 1.50	0.85
20°	5.99 ± 4.25	5.61 ± 2.70	6.57 ± 3.64	0.95

(alpha = 0.05)

The stability values presented in Table 7 were calculated from the differences between the injured knee and the same knee

Figure 16

Mean Anterior Mid-Range
Stiffness Differences

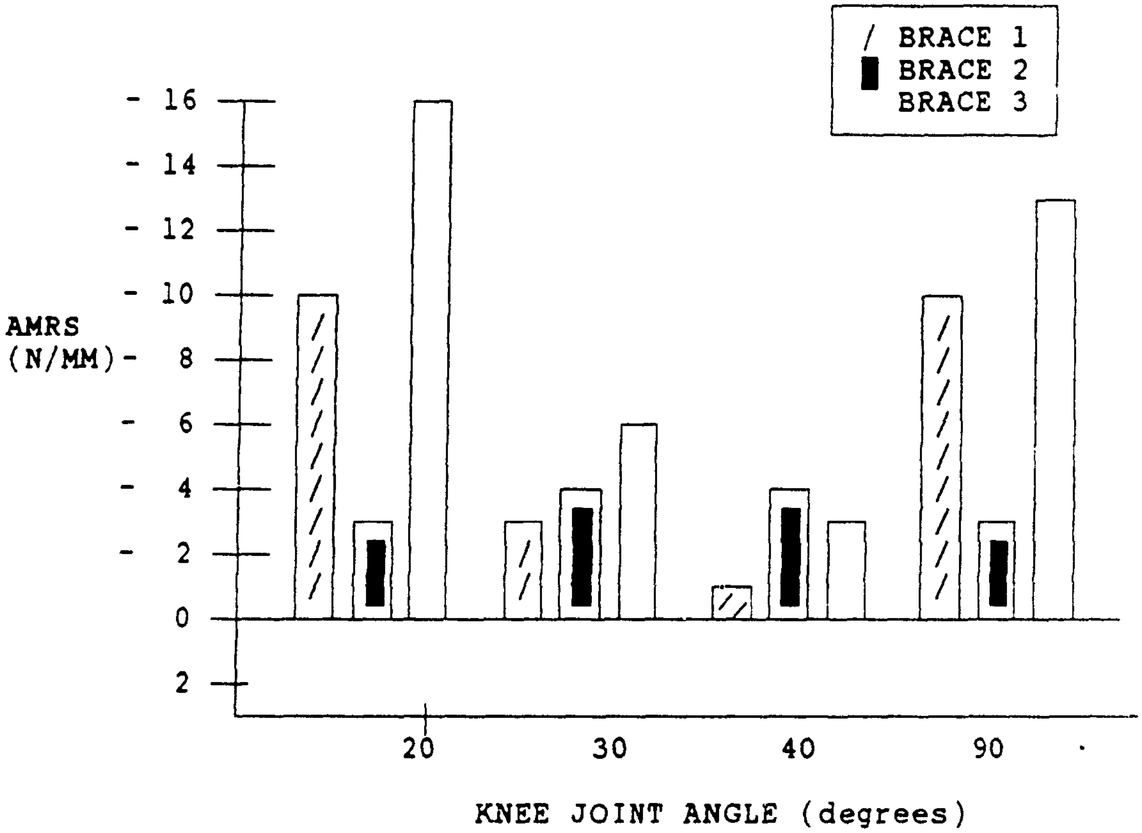


Figure 17

Mean Anterior End-Range Stiffness Differences

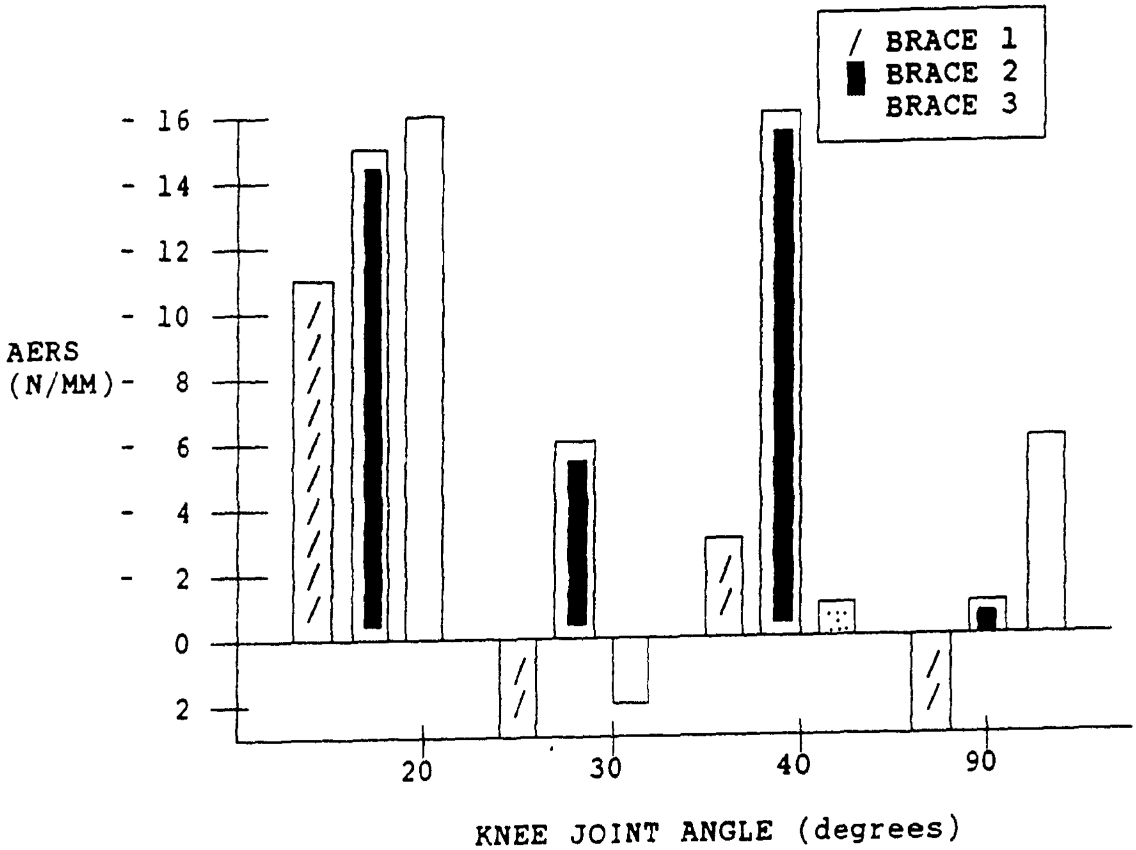
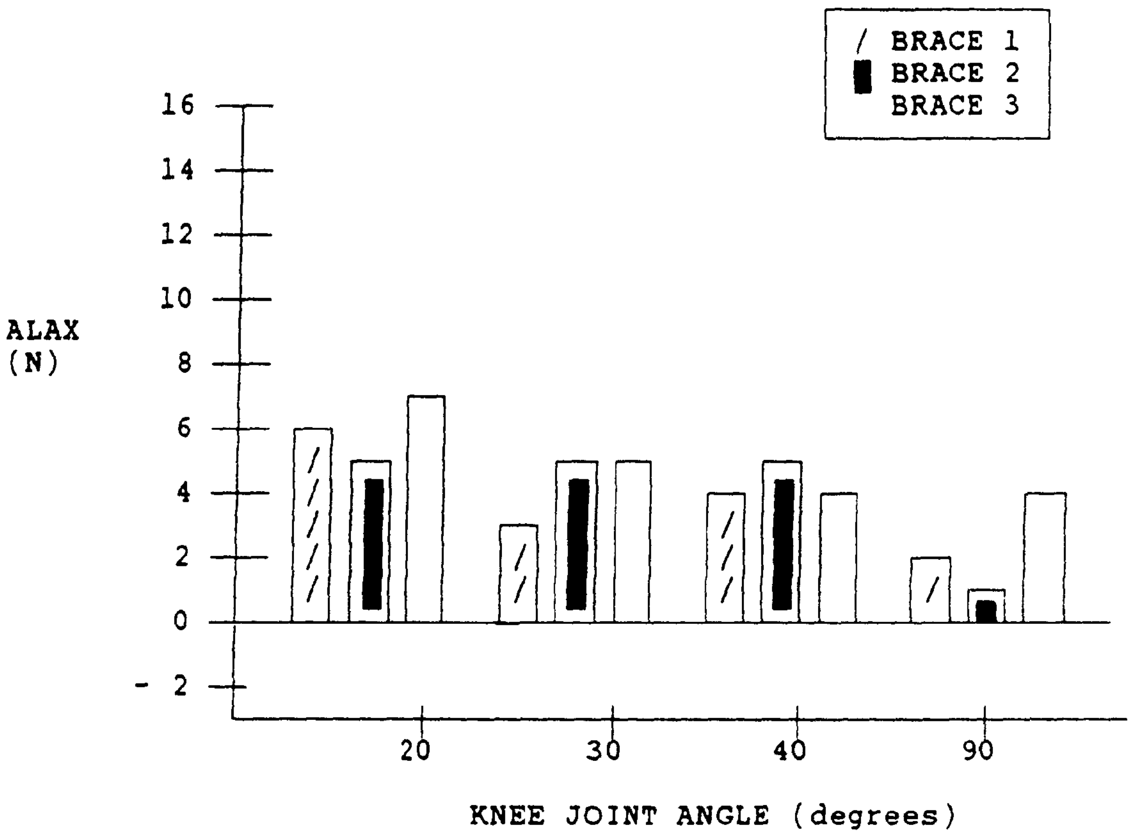


Figure 18

Mean Anterior Laxity
Differences



fitted with a brace. It should be noted that the mean differences detailing the stiffness profiles decrease as the effect of the brace increases. This relationship changes for the laxity profile. That is the mean differences in laxity increase as the effect of the brace increases.

Figure 17 illustrates the AERS differences provided by the three braces. As demonstrated, large differences occur between the three braces at 30°, 40° and 90°. The positive differences at 30° indicate that the involved knee without a brace produced greater stiffness than when fitted with brace 1 and brace 3. Similarly, at 90° flexion, the involved knee elicited a greater stiffness value than when fitted with brace 1. This phenomenon could be explained as a result of the neutral point.

Finally Table 7 details the descriptive statistics for ALAX across the three braces. Once again, no significant differences were obtained between the three knee braces at each flexion angle.

As shown in Figure 18, the three braces provide similar stability patterns at each flexion angle. Overall the three braces provide less stability as the knee joint approaches extension.

4.5 A COMPARISON AMONG THE THREE KNEE BRACES FOR LAXITY AND STIFFNESS VALUES DURING INTERNAL ROTATION

Table 8 details the descriptive statistics for internal rotatory laxity (ILAX) and translation of the lateral tibial plateau during rotation (TLTP) at 90°.

No significant differences were found between the braces at 90° flexion for both ILAX and TLTP. The differences for ILAX were similar across the three braces. The stability provided by brace 1 was less than three degrees greater than brace 3 and less that one degree greater than brace 2. Figure 19 and 20 illustrate the stability differences across the three braces for ILAX and TLTP.

TABLE 8

DESCRIPTIVE STATISTICS FOR ILAX AND TLTP

STABILITY (Involved - Brace)				
	Brace 1	Brace 2	Brace 3	
Flexion Angle	$\bar{X} \pm$ S.D N=5	$\bar{X} \pm$ S.D N=3	$\bar{X} \pm$ S.D N=3	F SIG
ILAX (°)				
90°	-4.05 ± 9.18	-4.55 ± 6.46	-6.65 ± 4.80	0.83
TLTP (MM)				
90°	-0.69 ± 2.69	-1.80 ± 3.73	-0.28 ± 8.49	0.92

(alpha = 0.05)

Figure 19

Mean Internal Laxity Differences

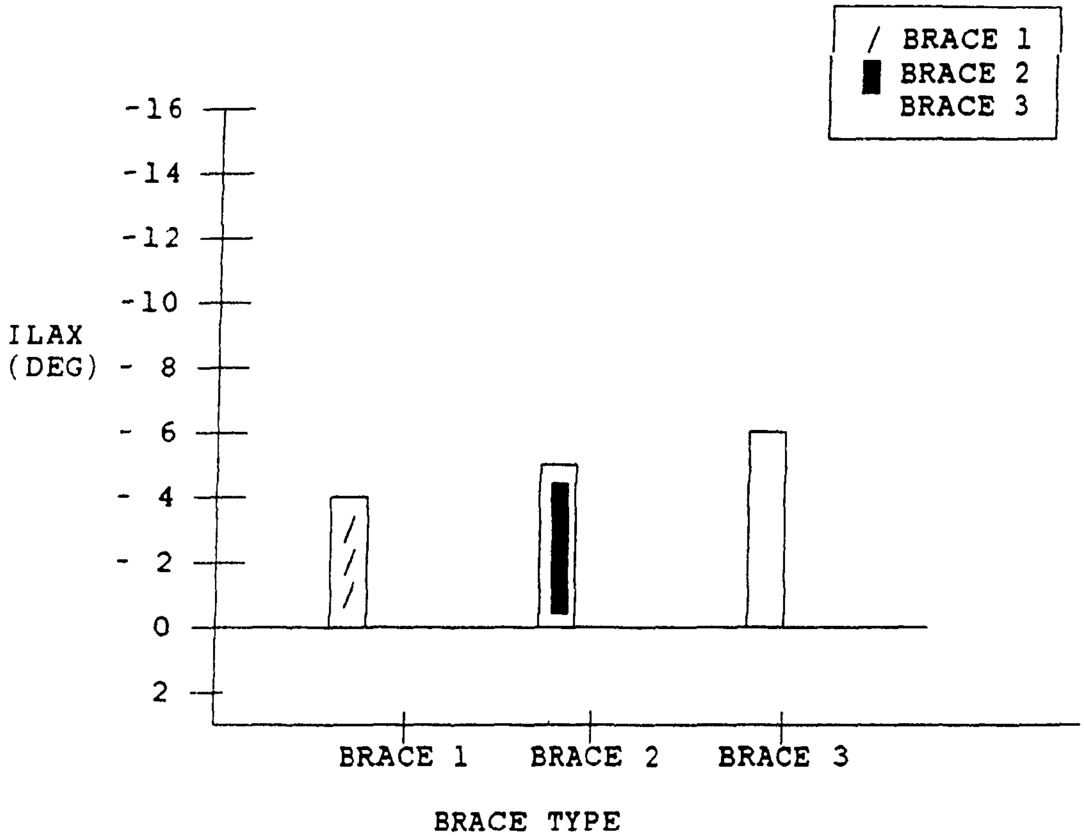
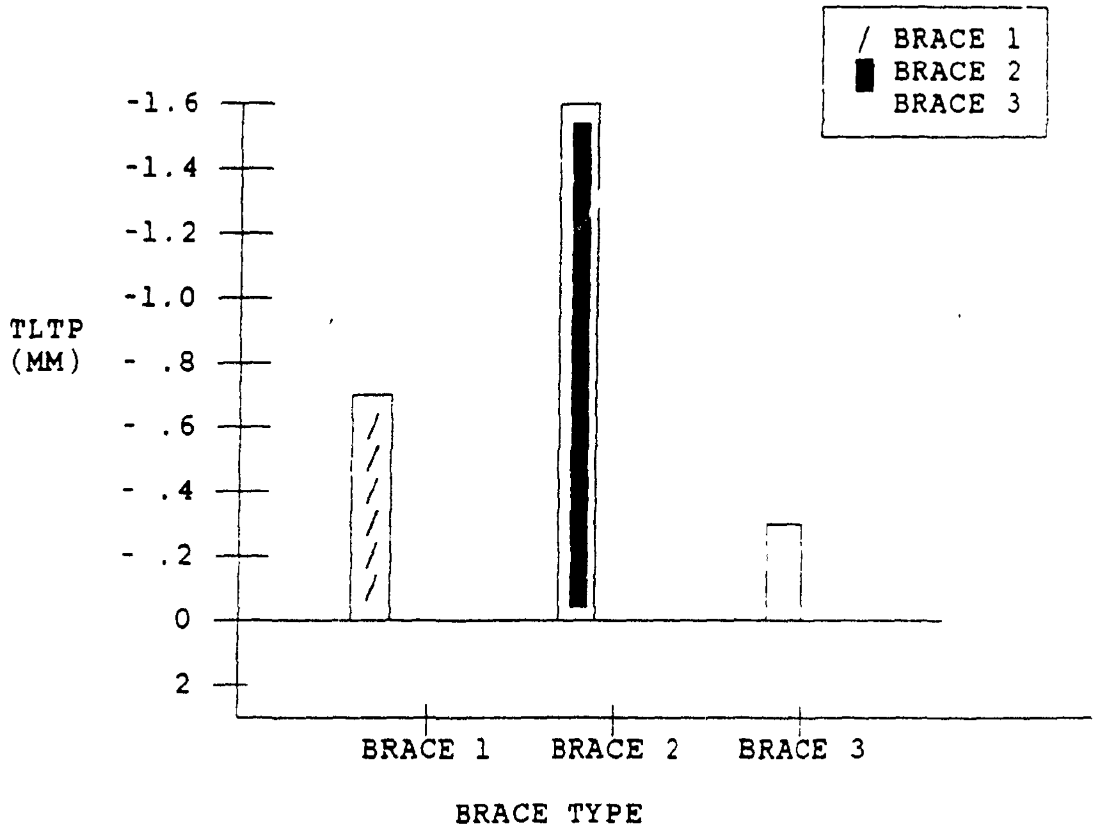


Figure 20

Mean Translation of the Lateral
Tibial Plateau Difference



CHAPTER V

DISCUSSION OF RESULTS

The focus of this study was to objectively evaluate and compare stiffness and laxity profiles of three functional knee braces designed to control translational and rotational instabilities reflective of an ACL injury. This chapter will provide a discussion of the procedures and results of the investigation. The topics of discussion are the following: 1. hypotheses and results of section 4.3, 2. hypotheses and results of section 4.4, 3. hypotheses and results of section 4.5, 4. comparison of results to current research, and 5. application of results.

5.1 HYPOTHESES AND RESULTS OF SECTION 4.3

The efficacy of functional knee braces, in maintaining translational stability throughout a range of motion, was evaluated using anterior laxity and stiffness measurements. The angles under investigation were 20°, 30°, 40° and 90° flexion. The most important aspect of this testing was to determine whether the effect of the brace on the deficiency differed significantly throughout a range of motion. This analysis involved a one way ANOVA of the criterion variables; ALAX, AMRS and AERS across flexion angle for each individual brace. The criterion variables ALAX, AMRS and AERS were derived from measurement differences between the intact knee and injured knee fitted with a brace. This procedure allowed the contralateral intact knee to serve as a control measure between the three subject groups fitted with a different brace.

5.1.1 HYPOTHESIS I

There is no significant difference between anterior laxity values obtained at four flexion angles for each brace.

This hypothesis was accepted (alpha=0.05) based on the non significant F value shown in Tables 4, 5 and 6 for brace 1, brace 2 and brace 3, respectively.

5.1.2 HYPOTHESIS II

There is no significant difference between AMRS and AERS values obtained at four flexion angles for each brace.

Once again Tables 4, 5 and 6 reveal non significant F values for brace 1, brace 2 and brace 3. This leads to the acceptance of hypothesis II (alpha=0.05).

5.2 HYPOTHESES AND RESULTS OF SECTION 4.4

The preceeding section focused on the individual effectiveness of the three braces in controlling translational instabilities throughout a range of motion. The following analyses takes this investigation one step further and compares the effectiveness across the three braces. The significance of this procedure was to differentiate between brace 1, brace 2, and brace 3 based on their ability to control translational laxity and stiffness profiles of the knee. One way ANOVA's were performed across the three braces for each criterion variable; ALAX, AMRS and AERS. Each analysis was done with the tibia and femur angled at 20°, 30°, 40° and 90° flexion.

5.2.1 HYPOTHESIS III

There is no significant difference between anterior laxity values obtained by brace 1, brace 2, and brace 3.

This hypothesis was accepted (alph=0.05) based on the non significant F values shown at the bottom of Table 7.

5.2.2 HYPOTHESIS IV

There is no significant difference between AMRS and AERS values obtained by brace 1, brace 2 and brace 3.

This hypothesis was accepted for AERS values (alpha=0.05), based on non significant differences between the three braces shown in Table 7. However, Table 7 also revealed a significant F value across brace types for AMRS. A post hoc Tukey test indicated that significant differences occured between brace 1 and brace 3 and also between brace 2 and brace 3, at 20° flexion.

5.3 HYPOTHESES AND RESULTS OF SECTION 4.5

The final analyses investigated the differences between the three braces in maintaining rotatory stability. The criterion variables were internal rotatory laxity, ILAX, and translation of the lateral tibial plateau, TLTP. The analysis involved two one way ANOVA's across the three brace types. Both procedures were performed at 90° flexion.

5.3.1 HYPOTHESIS V

There is no significant difference between internal laxity values (ILAX) obtained by brace 1, brace 2 and brace 3.

This hypothesis was accepted (alpha=0.05) based on the non significant F value of 0.83 shown in Table 8.

5.3.2 HYPOTHESIS VI

There is no significant difference between anterior translations of the lateral tibial plateaus obtained by brace 1, brace 2 and brace 3.

Once again, the hypothesis was accepted (alpha=0.05) based on the F value illustrated in Table 8.

5.4 COMPARISON OF RESULTS TO CURRENT RESEARCH IN THE AREA

The descriptive and statistical results of this investigation cannot be fully justified without comparing them to results obtained by other researchers within the field.

Designing knee braces to stabilize ACL deficiencies is not a new concept. However, it is only in recent years that a great emphasis has been placed on incorporating the biomechanical principles of an ACL into an external orthoses. This has resulted in a greater number of studies addressing the effectiveness of knee bracing, based on characteristics detailing the functional synergistic components of the ACL and surrounding structures.

This section presents some investigations which are comparative to the present study.

5.4.1 ANTERIOR LAXITY MEASUREMENT RELATED RESEARCH

Instrumented measurement of anterior knee laxity to evaluate the effectiveness of the Lenox Hill brace in treating an ACL deficient knee was investigated by Colville and company (1986). A sample of 45 patients were reported to have an average anterior displacement of 9.2 ± 3.8mm for the injured knee compared to 4.6 ± 1.9mm for the opposite intact knee, at 20° knee flexion and 100N of anterior force. The average paired difference (deficiency value) of 4.7 ± 3.5mm compared closely with the deficiency value of 4.45 ± 2.94mm reported for the subject sample fitted with brace 2. However, the value differs greatly from the displacement differences of 8.60 ± 2.33mm and 2.94 ± 2.34mm for subject samples fitted with brace 1 and brace 3, respectively. The differences in displacement between the three brace groups were not significant. The differences in deficiency values between the three braces seem to suggest different knee pathologies between subject groups.

Colville (1986) also found that the average displacement of 9.2mm without the brace changed to 6.5 ± 2.4mm in the brace, a change of 2.7 ± 2.4mm or 29%. These results differ comparatively with the results of the present study. This study reported a greater change in mean anterior laxity values between the injured knee compared to the same knee fitted with a brace (brace 1: 70%, brace 2: 126% and brace 3: 223%). The differences in these scores may be attributed to the following: 1. small sample size (eleven subjects), 2. differences in knee pathologies between subject groups , 3. high variance in laxity due to a combination of injuries and not solely an ACL rupture and 5. brace design.

Today, a greater number of knee braces are designed with four-point suspension forces, including the three braces evaluated in this study. Depending on where the suspension forces are placed the orthoses will control anterior or posterior subluxation of the tibia (Schafer et al., 1988). It is important to know that unlike brace 1 and brace 2, brace 3 was designed with a tibial strap which wrapped anteriorly across the proximal end of the tibia. brace 1 and brace 2 were designed such that the strap wrapped posteriorly across the proximal end of the tibia. According to the proposed force system described by Schafer and coworkers, the design of brace 3 would result in a preloading of the tibia anteriorly.

Thus, the enormous differences in the mean anterior laxity values between deficiency and brace effect may be a result of the four-point suspension forces generated by brace 3.

In another invivo study, Beck et al., (1986) investigated the ability of seven functional knee braces to control anterior laxity for subjects with an ACL insuffiency. A comparison of the involved knee fitted with a brace to the normal knee generated the following brace effect results: 1. Don Joy 4-point, 0.33mm; 2. Generation II, 1.07mm; 3.RKS, 1.93mm; 4. Lennox Hill, 1.90mm; 5. Feanny, 2.80mm; 6. CTi, 2.23mm; and 7. Lerman, 2.47mm. These values were close to the values reported in this investigation except for the group fitted with brace 3 (brace 1, 2.61mm; brace 2, 1.16mm; and brace 3, -3.63mm). The negative value reported for brace 3 implies that the injured knee fitted with the brace provided decreased laxity compared to the uninjured knee.

In most clinical practices a brace is evaluated at 20° knee flexion and not often at angles approaching flexion. Hoffman et al.,(1984) studied the ability of six orthotic knee braces to stabilize anterior cruciate and medial collateral deficient cadaver knee specimens. In their research they evaluated that the injured knee fitted with a brace relative to the uninjured knee provided a greater stability at 90° than when measured at 40° knee flexion. This observation was consistent with the results obtained in the present study for brace 1 and brace 2, however, not for brace 3.

The preceeding investigation seems to confirm the notion that the differences in performance between the braces may be a result of brace design, fitting procedures, varying knee pathologies, and anatomy differences, between subject groups.

5.4.2 ANTERIOR STIFFNESS MEASUREMENT RELATED RESEARCH

Clinical testing of anterior stiffness profiles to evaluate the effectiveness of knee braces in stabilizing ACL deficiencies is not a common procedure. There has been some investigation of AMRS and AERS values for injured and uninjured knees, however, no investigations have studied the stiffness characteristics of a brace.

The present study revealed varied stiffness results across the three braces, paticularly for brace 3. Furthermore, the only significant differences in the investigation occured in AMRS values between brace 1 and brace 3 and also between brace 2 and brace 3. In general the AERS values for all three braces were characterized by large fluctuations. Unfortunately, there are no results within the literature for comparison, yet, the following implications can be made based on the present findings.

The differences in stiffness profiles can be attributed to a number of factors. The primary influencing factors include: 1. variation in alignment between the orthotic joint and the natural knee joint motion, 2. high variance in stiffness values due to the injury of more than one structure, 3. small subject sample and 4. difference in knee anatomy.

When an orthotic knee joint is unable to follow the motion of a normal knee joint, pistoning forces are produced causing discomfort, restricted motion and misalignment of the orthosis. In a recent investigation by Schafer et al., (1988) they report that orthotic joint designs such as: single axis hinges, posterior offset hinges and polycentric hinges all produce pistoning constraint forces above the normalized mean. Furthermore, results show that there were no significant differences among the pistoning forces of the three orthotic joint designs. All three braces evaluated in the present study are designed with polycentric hinges. Based on Schafer's findings the inconsistent patterning of the stiffness results for all three braces may be a result of the pistoning constraint forces generated by incorrectly aligned orthotic joints. However, studies have also indicated that even correctly aligned orthotic joints can cause constraints (Walker et al., 1985).

Walker and company used a graphics program to design external joints with certain parameters optimized, based on a three-dimensional model of the knee. It was found that polycentric hinges simulate a motion which reflects the changing instant center of the knee, however, this is done through a translational axis. The simulated movement does not consider the axial rotation which occurs at the same time as the translation of the femur. The authors proposed that polycentric hinges simulate abnormal knee motion by causing posterior translation on the lateral side of the femur and anterior translation on the medial side during flexion (figure 21).

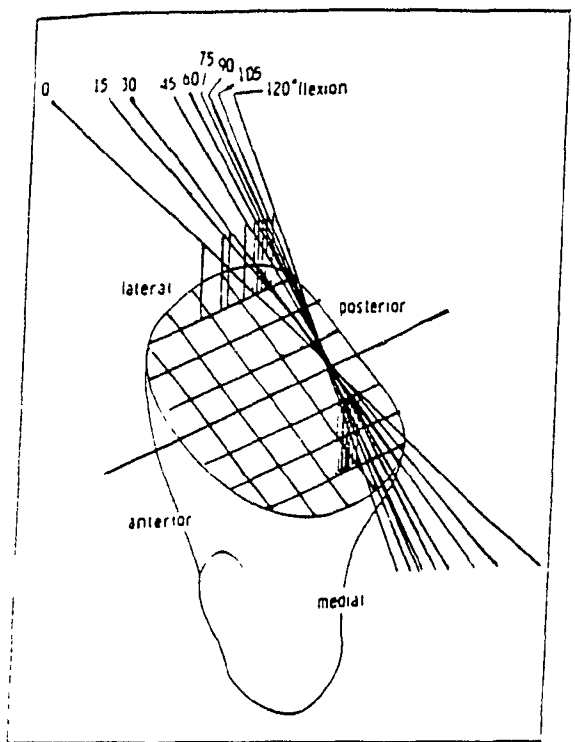


Figure 21

A scaled graphical representation of the reference transverse axis of the femur relative to the tibia during flexion from 0 to 120 degrees in 15 degree increments (Taken from Walker et al., 1985)

5.4.3 INTERNAL ROTATORY LAXITY AND TRANSLATION OF THE LATERAL TIBIAL PLATEAU RELATED RESEARCH

Documentation of the effects of knee braces on ACL injured knees in stabilizing rotatory instabilities is poor in comparison to the number of studies which have reported knee brace contributions to anterior laxity (Knutzen et al., 1984).

Knutzen and company collected maximum rotation values for healthy limbs, injured limbs and braced limbs, with the tibia and thigh angled at 90°. In their research they reported that both support and derotation braces created a decrease in external rotation and an increase in internal rotation, suggesting that the braces were exerting some form of external control. The results obtained in this study contrast with the results described by Knutzen. In the present investigation the mean internal laxity differences between the injured knee and injured knee fitted with a brace were -4.05°, -4.55° and -6.65° for brace 1, brace 2 and brace 3, respectively. It is important to remember that the mean differences detailing internal laxity decrease as the effect of the brace increases. Thus, it can be surmised that the brace is providing a constraint to internal rotatory movement. A stastical analysis confirmed that no significant differences existed between the braces.

In addition to rotatory instabilities, ACL ruptures result in a combination of translational and rotational instabilities, otherwise known as an antero-lateral instability. In the present study, antero-lateral irsufficiencies are characterized by the translation of the lateral tibial plateau during internal rotation. The values reported in Table 8 are consistent with the internal laxity measurements. This would be expected, since antero-lateral instabilities are a combination of internal rotatory laxity and anterior laxity of the tibia. The findings further support the assumption that the braces may be preloading the tibia externally.

5.5 APPLICATION OF RESULTS

The results of this investigation present some interesting findings. Overall the results do not provide many statistical significances between the performance of the three braces, however, the results do identify erratic patterning of stiffness characteristics for each brace. This lends support for further investigation using a variety of protocols to quantify the efficacy of bracing ACL injuries. In particular, investigations focusing on joint designs and four point suspension forces are needed to comprehend the pistoning and preloading effects which are altering the biomechanics of the knee.

Functional knee braces are intended to protect and stabilize the unstable knee. The findings of this investigation show that custom fitted knee braces do not restore normal knee stability and consequently, may be increasing the chances of reinjury. It might also cause injury if employed over long periods of time by causing abnormal motion of the knee joint.

CHAPTER VI

SUMMARY AND CONCLUSIONS

Knee braces have become a popular form of protection for ACL injured knees, even though little evidence supports their effectiveness. Scientific studies which test the effectiveness of functional knee braces are limited to clinical simulations and lack adequate protocols for an objective evaluation.

The purpose of this study was to implement a methodology which would objectively evaluate the ability of three functional de-rotational knee braces to control translational and rotational instabilities characteristic of an ACL injury. Also, to objectively evaluate the effect of three brace designs in controlling the instabilities.

6.1 METHODS AND ANALYSIS

This investigation involved an assessment of three functional knee braces, where three subject groups were fitted with a different brace. The study consisted of a randomized block design where five subjects were fitted with brace 1, three subjects were fitted with brace 2 and another group of three subjects were fitted with brace 3. The eleven subjects were chosen from a sample of fifteen, based on inclusion parameters. The data for each subject was obtained using the Genucom knee analyzer.

The first part of the investigation focused on how effectively each individual orthosis compensated for decreases in stiffness and laxity parameters throughout a range of motion. Each subject's intact knee, injured knee and injured knee fitted with a brace were evaluated three times and the average taken as the individuals score. Then, the average brace score was calculated for the five subjects fitted with brace 1, three subjects fitted with brace 2 and three subjects fitted with brace 3. The analysis involved one way ANOVA's of the criterion variables: ALAX, AMRS and AERS, across four flexion angles (20°, 30°, 40° and 90°). Post hoc Tukey tests were performed between flexion angles.

The second part of the investigation compared the three braces. Once again the subject's intact knee, injured knee and injured knee fitted with a brace were evaluated three times, averaged and mean scores taken for brace 1, brace 2 and brace 3. The analysis of the translational parameters involved one way ANOVA's of the criterion variables: ALAX, AMRS and AERS, across the three braces, at 20°, 30°, 40° and 90° flexion. The analysis of the rotational parameter involved one way ANOVA's of the criterion variables: ILAX and TLTP, across the three braces, at 90° flexion, followed by post hoc Tukey tests.

6.2 RESULTS

The first part of the investigation revealed the following statistical and descriptive results:

1. Brace 1 provided the greatest restraint to ALAX at 20° flexion. However, there were no significant differences between flexion angles.

2. The AMRS values were consistent when subjects were fitted with brace 1, whereas the AERS values were characterized by large fluctuations. None of the results were significantly different across the four flexion angles.
3. Brace 2 decreased mean ALAX values throughout the range of motion, paticularly at 90° and 20° flexion. The results showed that the injured knees fitted with brace 2 provided a greater restraint than the uninjured knees. There was no significant difference between the four flexion angles.
4. Both AMRS and AERS profiles showed inconsistent values for subjects fitted with brace 2. However, the patterning of both profiles were similar at 20°, 40°, and 90° flexion. The similarity being a greater restraint provided by the injured knee fitted with the brace compared to the uninjured knee. Once again there were no significant differences between flexion angles.
5. Brace 3 provided a restraint to ALAX, but it varied considerably across the four flexion angles. Also, the injured knee fitted with brace 3 provided a greater restaint than the uninjured knee. The values were not significantly different across flexion angles.
6. The effect of brace 3 on the stiffness profiles was considerably different. The AERS values were characterized by larger fluctuations compared to the

AMRS values. No significant differences were obtained between flexion angles.

In the second part of the investigation the following statistical and descriptive results were obtained:

1. There was a significant difference between mean AMRS scores of the three braces. A post hoc Tukey test revealed that the differences occured between brace 1 and brace 3 and also between brace 2 and brace 3. There were no significant differences between mean AERS and ALAX values of the three braces
2. The was no significant difference between the three braces for ILAX and TLTP values. However, all three braces fitted on the injured knee provided some type of control for internal rotation.

6.3 CONCLUSIONS

On the basis of the results obtained in this study, the following conclusions are justified.

1. None of the braces caused significant differences in laxity profiles throughout the range of motion.
2. None of the braces caused significant differences in stiffness profiles throughout a range of motion, however, the different braces resulted in different patterning.
3. Brace 1 and brace 2 produced significantly different

scores in AMRS compared to brace 3.

4. The remaining characteristics: ALAX, AERS, ILAX, and TLTP , did not distinguish significant differences between the three braces.

5. All three braces are exerting some form of control for internal rotation.

6.4 IMPLICATIONS

The following implications regarding strategies for protecting the knee joint from further injury are based on the results presented in this study.

The data presented within, suggests that the variations in laxity and stiffness profiles of the knee joint when a brace is fitted preclude effective control of such characteristics. Measurements might be improved by developping a better way of fitting a brace to decrease the forces causing abnormal motion of the knee joint and controlling parameters which establish negative effects of such forces. One such strategie may be to control the range of motion of the knee joint thus decreasing the number of forces at the knee joint. Such an investigation would provide greater knowledge of the ability of the brace to control the rotational and translational characteristics of the knee joint.

6.5 RECOMMONDATIONS

1. Additional investigations to establish the contributions of external forces on the knee joint throughout a range

of motion.

2. Research is needed to compare the instantaneous center of the knee with that of the brace, to verify that they follow the same path.

3. More research should address the placement of 4-pt suspension forces and their effect in stabilizing and preloading the tibia.

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APPENDIX A

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 knee joints by the examiner in a series of clinical tests. A maximum force of 33 lbs. will be applied to the joint. Additionally, the thigh muscle will be restrained by the device. The other non-invasive testing device to be used in this study is the cybex. This isokinetic machine will be used to measure the amount of force generated by the thigh muscle while the brace is applied. Also, you will be asked to demonstrate two functional activities: jumping and kicking. These will be filmed.

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 your discretion 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 signiture below reflects my consent to be a participant in this study.

Signature:____________________________

Date:______________________

Address:____

Telephone:____________________________