AN EVALUATION OF FOUR KNEE LAXITY TESTING PROCEDURES
FOR CRUCIATE LIGAMENT INSUFFICIENCY

by

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ABSTRACT

The purpose of this study was to compare reliability and validity of three knee ligament laxity testing devices, the classical clinical examination for anterior posterior laxity, and radiographic stress tests for anterior-posterior laxity at 30 degrees of knee flexion. The clinical evaluation was performed by an experienced orthopaedic surgeon and assessed with a modification of the grading system used by Houghston (1976). The four objective testing procedures employed were: 1) the Genucom knee analysis system, 2) the Stryker anterior-posterior knee testing device 3) the KT 1000 Knee Arthrometer and 4) Radiographic stress tests. A sample of fifteen male patients with unilateral anterior posterior knee laxity were evaluated using all five measurement procedures. The magnitude of anterior-posterior (A/P) displacement was tabulated in accordance with the modified grading scale in the clinical exam, while the radiographic tests and the three instrumented devices provided measurements in millimeters. The first part of the investigation established the repeatability of the three instrumented devices over a two day testing period. An ANOVA indicated that there was no significant main effect over the factor of DAY but that there was a significant effect over the factor of DEVICE (Genucom, KT1000 and Stryker). Post hoc contrasts showed that the Genucom scores differed significantly (Scheffe 0.05) from both the KT1000 and the Stryker while the KT1000 and the Stryker showed no significant differences between mean scores. This was the case for the analysis of the single subject-ten repeat scores and the ten subject ANOVA. The second part of the investigation consisted of a two factor ANOVA which assessed all five measurement procedures over the normal and cruciate deficient knee populations. A significant difference was found in the factor of knee which would lead us to infer a significant laxity difference in normal and cruciate deficient knees. A significant difference was also found in the measurement procedure factor. This led to post-hoc comparisons which were corrected for experiment-wise error with a Scheffe test. In the group of normal knees all of the measurement scores significantly differed from each other except for the comparison of the KT1000 with the Stryker, (alpha= 0.05) while in the group of cruciate deficient knees, the clinical with the KT1000 and the clinical with the Stryker were also not significantly different (alpha=0.05). These results would seem to indicate that there is much variation due to test procedure but that all test procedures have the ability to indicate a significant difference between normal and cruciate deficient knees.

RESUME

La présente étude visait à évaluer la fiabilité et la validité de trois systèmes d'évaluation de l'intégrité ligamentaire du genou en flexion de 30, soit: le système d'analyse du genou GENUCOM, le "Stryker knee laxity tester" et l'arthrometre KT1000. Plusieurs de ces appareils sont couramment utilisés pour évaluer l'amélioration consécutive à la chiurugie. Les résultats obtenus ont permis de calculer un coefficient de correlation de fiabilité de 0,73; 0,78; et 0,75 respectivement, pour le Genucom, le KT1000, et le Stryker. De plus, 15 patients masculins souffrant d'une déficiance unilatérale du croisé antérieur ont été soumis à un examen clinique ainsi qu'à une évaluation répetée sur chacun des appareils considérés. Les déplacements antérieur et postérieur étaient quantifiés à l'aide d'une échelle graduée pour l'examen clinique tandis qu'ils étaient rapportés en mm pour les appareils. Les résultats ont permis de mettre en évidence une différence ($p < 0.05$) entre le genou sain et celui atteint d'une déficiance ligamentaire, peu importe le test utilisé bien que l'importance des déplacements soit différente selon le test utilisé. Une comparaison post-hoc à en effet démontré une différence entre chacun des tests sauf pour le KT1000 et le Stryker ($p < 0.05$). Ces résultat indiquent qu'il existe une différence dans l'importance des déplacements mesurés à l'aide des différents systèmes de mesure bien que chacun des tests permette de mettre en évidence une différence entre le genou sain et le genou atteint d'une déficiance ligamentaire.

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CHAPTER I

1.1 INTRODUCTION

An objective procedure for measuring knee ligament laxity has been difficult to establish until the recent development of mechanical devices designed specifically for this purpose.

There is an abundance of pathological knee laxity literature investigating changes due to disrupted ligaments in vitro as there was previously no method for in vivo assessment. In the past decade, however, knowledge concerning the structural and functional relationships of ligaments surrounding the knee joint has increased substantially. Consequently, the ability to quantitatively measure in vivo laxity parameters is becoming increasingly important in diagnostic and operative orthopaedic medicine. The development of reliable, valid and objective testing apparati is essential for the evolution of orthopaedic research involving the knee.

Three such objective devices currently in use for the measurement of knee laxity are: the Stryker Knee Laxity Analyzer, the KT1000 knee Arthrometer and the Genucom Knee Analysis System.

Objective measures of knee laxity are important for the evaluation of surgical procedures, establishing group norms for use in diagnosis, cataloguing changes in knee laxity over time and the evaluation of rehabilitative procedures and knee braces.

1.2 NATURE AND SCOPE OF THE PROBLEM

Diagnosis of excess knee ligament laxity is most often made following a manual clinical evaluation of relative tibio-femoral movement in response to applied forces. This is a subjective assessment involving both proprioceptive and visual perception of movement between the two joint surfaces (Torg et.al. 1976). Obviously, the quantifiable accuracy of such a visual/proprioceptive technique is questionable.

The demand for objectivity in knee joint assessment has increased with the amount of research concerning the knee, and resulted in a number of instruments being designed for measuring laxity of the knee ligaments. Three such devices are the Genucom Knee Analysis System, the Stryker Knee Laxity Tester and the KT1000 Knee Arthrometer. These instruments have the added potential of being able to identify previously undetected structural differential subtleties in laxity parameters of damaged knee joints. Objective measures have implications for the development of new diagnostic techniques and the evaluation of the effects of surgical procedures for the correction of laxity-related instability. Populations such as football and hockey players could possibly be screened for knee laxity which is associated with increased propensity to ~~knee~~ injuries (Nicholas, 1970).

The initial significance of improved knee laxity quantification is that it challenges the efficacy of the traditional subjective clinical assessments. Therefore the reliability, validity and objectivity of the new devices must be scientifically established.

In this study, variation of the measures from each of the test methods were characterized in light of the reliability and validity. Variation consisted of two parts: directional (or biased) variation and random variation. Subsets of random variation include both natural subject variance and measurement variance. Measurement variance can be a result of either equipment or experimentor (measurement) error in the collected data.

As the parameter assessed in this experiment was the range of tibial displacement on the femur, the criterion measurement was the visual display of that displacement (provided through the radiographic procedure). Therefore, validity was measured through single degree of freedom comparisons of each measure with the radiographic measure and with each other.

1.3 STATEMENT OF THE PROBLEM

The problems addressed in the study include:

a) Is there a significant difference between the A/P laxity test at thirty degrees of flexion for the five measuring procedures and for injured and uninjured knees?

b) What are the variance characteristics of each measuring procedure over trials?

c) How do the four measurement procedures compare to the criterion radiographic technique?

d) How do the five measurement procedures compare to each other?

The experimentor investigated these problems with the following objectives;

A. To determine the differences among the classical Lachman's test for anterior-posterior laxity at 30 degrees of knee flexion, and three mechanical measuring devices all of which simulate the Lachman's test: the Genucom, the Stryker, and the KT 1000 knee ligament testers.

B. To determine the variance in the measurements obtained by the three devices when all are used to assess the same sample populations of both uninjured and cruciate deficient knees (variance within, over trials, and over each apparatus).

1.4 HYPOTHESES

1. There will be no significant difference in Day 1- Day 2 test scores for the Genucom, Kt1000 and Stryker knee ligament laxity testers.
2. There will be no significant difference between the measurements obtained by the Genucom, Stryker, KT1000, radiographic and Lachman's tests.
3. There will be no significant simple main effect between the injured and the non-injured knees tested.

1.5 LIMITATIONS AND DELIMITATIONS

LIMITATIONS:

1. The major limitation of this study is that it is confined to only one ligamentous laxity test over one specific angle and force application.
2. The external validity of the study is limited by the presence of two factors: i) the clinical exam was performed by only one orthopaedic surgeon, ii) the laxity tests with the instrumented devices were performed by a single trained evaluator, and iii) the force used to evaluate displacement was set at twenty pounds.

DELIMITATIONS:

1. As the subjects included males only, this would remove the aspect of gender variance.
2. A single operator of the devices would similarly remove intra-operator variance.
3. The set force at 20 lbs would remove the variance found in the clinical test.

1.6 OPERATIONAL DEFINITIONS

Anterior-posterior translation

- the displacement of the tibia relative to the femur when a force is applied parallel to the joint surfaces.

A/P

- anterior-posterior direction, a direction perpendicular to the long axis of the tibia and parallel to the sagittal plane.

M/L

- medial-lateral direction, a direction perpendicular to the long axis of the tibia and perpendicular to the sagittal plane.

C/D

- compression-distraction, a direction corresponding to the long axis of the tibia through its centre.

V/V

-varus/valgus, a direction around the anterior/posterior axis.

Internal/external

- a direction around the long axis of the tibia.

Relative laxity

- the anterior-posterior displacement of the diagnosed anterior-cruciate deficient knee as compared to the normal knee.

Physiological

- denotes active muscle contraction

Effusion

- a swelling of the knee joint most often arising as a result of internal derangement.

CHAPTER II

REVIEW OF THE LITERATURE

2.1 INTRODUCTION

The function of the knee joint is dictated by many factors. These factors include muscular dynamics, bony contour, articular cartilage, and ligament restraint. Since the purpose of this study was to evaluate methodology of ligament restraint assessment, the specificity of the Lachman's test and how it relates to the biomechanics of the knee joint is presented within this section.

2.2 KNEE FUNCTION

The knee performs many functions in its normal capacity including, flexion, extension, rotation and shock absorbtion. As with many anatomical structures in the body, the knee joint and its surrounding structures are subject to a large amount of individual variation. In spite of these variations, the functional systems, or functional synergies of knee movement, remain relatively constant.

Structural or functional synergies in the knee occur between the menisci, ligaments, and bony configuration. Close interaction between these structures leads to variable strengths and weaknesses of each with complementary, compensating strengths to ensure adequate controlled degrees of freedom and restriction of movement in the knee.

2.2.1 DYNAMIC AND STATIC LIGAMENTS

The concept of dynamic and static ligaments is important in understanding the complex nature of the supportive structures in the knee. Static ligaments refer to those which are not incorporated into the contractile tissue. Alternatively, dynamic ligaments (medial collateral, posterior oblique) are those which are integrated with contractile tissue, muscle fibers and tendons, (Warren and Marshall, 1978).

Muller (1985) found large differences between ligamentous tissue which is attached to bone (static), and those which are attached to tendon or muscle (dynamic); differences in the ratio of dynamic to static ligaments varied considerably in a sample population. It was suggested that the presence of a large number of dynamic ligaments could adequately account for the ability of an unstable joint to become functionally stable with increased muscle strengthening. Furthermore, the stronger the dynamic ligaments, the greater protection they will provide the static ligaments; an important consideration in rehabilitation therapy.

2.2.2 KINEMATICS

Throughout the literature, it is generally agreed that motion at the knee joint is a combination of rotation, gliding and rolling between the tibia and the femur. Rolling and gliding appear to occur predominantly in the sagittal plane; but, it is often difficult to discern due to the superimposed rotation in the horizontal plane. Rotation occurs automatically at initial and terminal ranges of flexion, and is under voluntary control throughout the rest of the range of knee flexion. Many authors have studied the concept of simultaneous rolling and gliding as the knee moves through its range. Kapandji (1970) discussed the classical experiment done by the Weber brothers (1836) which showed that the tibio-femoral motion throughout knee flexion is a combination of rolling and gliding. This hypothesis was investigated by marking the points of tibio-femoral contact throughout the range of knee motion. Results illustrated that: 1) the point of contact on the tibial surface moved posteriorly as the knee flexion angle increased, and 2) the distance between points of contact on the femoral condyle was twice as far as the corresponding distance on the tibial condyle. It is clearly seen, from these results, that the femoral condyle rolls and glides simultaneously over the tibial condyles as the knee goes through the range of flexion. The gliding portion of this movement appears to allow the knee a greater range of flexion without posterior dislocation of the femoral head.

A four-bar linkage model can best illustrate the dominant movement of the knee in the sagittal plane. The model consists of the cruciate ligaments (represented by rigid bars) which are hinged on a line set at an angle of forty degrees to a given perpendicular. The fourth linked bar of this system is moveable and representative of the tibial plateau. This bar can be considered a coupler of the system. If tangential lines are drawn on the coupler as it moves through the available range, a "coupler envelope curve" can be delineated. This curve appears to approximate a sagittal section of the posterior half of the femoral condyle. If the fourth bar of the system, that which represents the tibial plateau, is curved to more accurately represent the tibia, a curve is generated which represents the articular surface of the femur more accurately (Fig.1). This model can also illustrate the varying ratio of rolling to gliding as the knee moves into flexion. The ratio changes from 1:2 in early flexion, to 1:4 by the end of flexion (Muller, 1984).

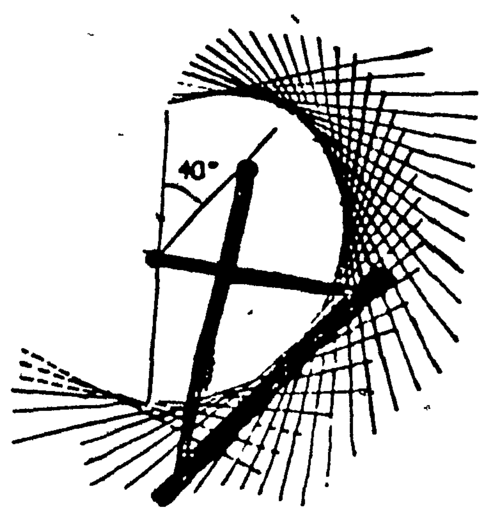

Figure 1. The Four Bar Linkage Model

As this model does not include the patella, its validity breaks down where the patello-femoral joint occurs at the anterior aspect of the joint, influencing the forces generated by the quadriceps.

Rotation at the knee joint is affected to some degree by almost every muscle acting on or around the knee joint. For example, the Q angle of the vastus lateralis and rectus femoris acting at approximately 10-15 degrees, exerts an internal rotation (IR) force on the tibia when the muscle contracts. This force is balanced by the vastus medialis which assists in neutralizing tibial rotation. An important pure rotator of the knee is the popliteal muscle which, when the tibia is free, rotates it internally, and when the tibia is fixed, controls antero-lateral tibial excursion.

Noyes et.al. (1980) discussed the concept of primary and secondary stabilizers for each plane of knee motion. The importance of the primary restraints must be considered when evaluating the damaged knee. This is due to the fact that the secondary restraints, although potentially able to restrict abnormal laxity, are unable to do so over a period of time and varying levels of stress. Therefore, the clinical identification of primary ligament insufficiency is critical to planning appropriate treatment.

2.2.3. ROLE OF THE CRUCIATE LIGAMENTS

The forces imposed by the placement and shape of the two cruciate ligaments, anterior cruciate (ACL) and posterior cruciate (PCL), are components of a functional synergy with the femoral and tibial condyles.

In relation to the afore-mentioned, four-bar linkage model, the cruciates functionally form two parts of the bars in the model. The end ranges of knee movement can also be defined by the cruciate ligaments. The femoral origins lie on a line which creates a 40 degree angle with the long axis of the femur. This allows for a range of motion from zero to 145 degrees of flexion. This placement angle of 40 degrees corresponds to the angle of the roof of the intercondular notch relative to the long axis of the femur. In full extension, the anterior cruciate is in line with the intercondular notch and therefore is in a position to restrict extension. Clinically, this puts the anterior cruciate ligament in a vulnerable position if the knee is hyperextended- especially if impinged against the " notch of Grant" (Grant and Basmajian, 1965). The clinical presence of pathological hyperextensibility in the absence of an intact cruciate ligament would seem to support this view. Alternatively, the posterior cruciate ligament is aligned with the roof of the intercondular notch in a position of maximal flexion. It is much less susceptible to injury due to its strength, and the approximation of posterior leg soft tissue when the knee is in maximal flexion.

Wang and Walker, (1973) measured length changes in the anterior and posterior cruciate ligaments in twelve cadaver specimens. Various joint angles were employed with pin insertions at specific points on the ligaments for visualization by radiographic technique. Results reported that the ACL gradually increased in length ten percent from zero to one hundred and twenty degrees of flexion; and the PCL was ten percent longer at zero degrees flexion than at all other lengths where it remained constant. This suggests a reciprocal action between the cruciates. The length changes seen in this study could be interpreted as tension changes with the increasing length, but no conclusive data has yet been presented to address tension changes in vivo.

Butler (1980) carried out an experiment designed to rank the restraining importance of the ligamentous and capsular structures which restrict anterior-posterior translation at both thirty and ninety degrees of flexion. It was reported that at the ninety degree flexion angle, the anterior cruciate provided 85.1 +/- 1.9 % of the restraining force to anterior translation, and the posterior cruciate provided 94.3 +/- 2.2% of restraint to posterior translation. At thirty degrees of flexion, the ACL restraint was 87.2 +/- 6%, and the PCL restraint 96 +/- .04%. The force/displacement was constrained to a position of neutral rotation in the tibia. This study provides an indication of the importance of the cruciates in restricting abnormal sagittal laxity. It must also be realized that, as with any in vitro assessment, the dynamic effects of the musculature have been eliminated; thus these results may not reflect in vivo situations. The next step in the investigation appears to be to test these parameters in vivo.

The investigation of the normal function of the cruciates, and their corresponding restraining forces, is important in selecting which stress test is most indicative of pathology.

2.2.4 ANTERIOR CRUCIATE

A great amount of emphasis has been placed on the anterior cruciate ligament due to its unique role in stabilizing the knee in the sagittal plane and it's frequency of injury.

Anatomically, the ligament consists of two discrete bands of fibers: the anteromedial and posterolateral bundles (Girgis et. al. (1975)). A selective cut of the anterior cruciate gives an increased anterior drawer in flexion and extension, increased internal and external rotation, and pathological hyperextension. It was suggested, (Grigas et al. 1975) that the anteromedial band of the ACL was responsible for the increased anterior-posterior drawer with flexion.

Cross and Norwood (1979) also investigated the functions of the discrete bands of the ACL . Three bundles of fibers, the anteromedial, intermediate and posterolateral bundles were studied. Functional assessment of the bundles provided the following information, the anteromedial bundle contributes to anterolateral stability, the intermediate bundle to straight anterior and anteromedial stability and the posterolateral bundle to posterolateral stability. Other studies supporting these conclusions on the function of ACL fiber bundles have been reported by Girgis et.al. (1975).

Of the five principal functions of the anterior cruciate ligament reported in the literature, the first and most critical is to resist anterior-posterior translation of the tibia on the femur (Ellison and Berg, 1985, Kennedy and Fowler, 1971). Kennedy and Fowler (1971) investigated anterior translation of the tibia on the femur through a roentgenographic technique comparing unstressed and stressed conditions. In a normal population, measurement of anterior displacement of the tibia on the femur ranged from 0.0 to 5.0 millimeters. On a subsequent investigation of abnormal knees, a group of seven subjects who presented with pure anterior translation (a range of 7.0 to 20.0 millimeters) had operative findings of isolated, damaged or completely disrupted anterior cruciate ligaments.

Fukubayashi et. al. (1982) explored the anterior-posterior motion at zero through ninety degrees in nine normal cadaver knees with dependent variables of tibial displacement, rotation and torque. Measurements reported of intact knees consistently showed that an anterior force produced an internal tibial torque and internal tibial rotation, while a posterior force produced an external force and external tibial rotation. When the ACL was selectively sectioned, over double the amount of anterior displacement was seen without any change occurring in posterior displacement.

The second function of the ACL is to prevent hyperextension as the posterolateral fibers become increasingly taut in extension,(Grigis et.al (1975)).

The third function of the ACL is to act as a check to internal rotation and thus provide rotatory control. Although the anterior cruciate ligament contributes predominantly to the control of rolling and gliding in the sagittal plane, it also plays a role in terminal knee extension by guiding the anatomical movement of external rotation of the lateral tibial plateau. This is commonly known as the "screw-home" mechanism which increases knee joint stability in preparation for weight-bearing (Muller 1983). This function is important to demonstrate that while acting as a anterior-posterior stabilizer, the ACL works in synergy with many secondary stabilizers.

In the study previously described, (Wang and Walker, 1973), ligament length patterns were also described during rotatory movement. Results showed a significant increase in anterior cruciate length during internal rotation when the knee flexion angle is greater than thirty degrees. This increase in length may indicate the ACL also acts as a restraint to internal rotation.

Shaw et.al. (1974) examined the longitudinal axis of the knee, and the role of the cruciates in controlling transverse rotation. Both voluntary rotation, which is possible at all angles of knee flexion, and the involuntary rotation associated with the locking of the knee in the thirty degrees prior to full extension, were examined. Results reported the anatomical axis of rotation as passing through the medial intercondular tubercle of the tibial plateau. Alternatively, specimens with sectioned anterior cruciate ligaments demonstrated irregular rotatory patterns in the involuntary pre-extension rotation of the "screw-home" mechanism. This irregularity is characterized by an anterior displacement of the tibia on the femur. The major axis of rotation with the ACL sectioned was difficult to discern but it is still in the proximity of the medial intercondular tubercle of the tibial plateau. When the PCL was sectioned, there was very little variation in the rotatory pattern from that seen with both cruciates intact. This led the authors to speculate on the dominant role of the ACL in controlling rotation. This study demonstrates the fourth major function of the anterior cruciate: to fine tune the "screw-home" mechanism in terminal extension.

The fifth major function of the anterior cruciate is a secondary restraint to varus-valgus forces in combination with the medial collateral ligament. This function is relatively minor and will not be elaborated upon in this review .

2.2.5 THE EFFECT OF CRUCIATE INSUFFICIENCY

Perhaps the best description of the cruciates function is a concept approached by Huson (1974), and Menschik (1975) in their discussion of the four bar linkage system: " The cruciates convert a true rotational movement into a more complex movement of the coupler".

Disruption of a cruciate ligament abolishes the "gear mechanisms" (axial function of the cruciates) at the knee. The loss of this function, according to Trillat (1978) and Menshik (1974) can not be sufficiently compensated for by the remaining structures.

An insufficiency of the anterior cruciate ligament will result in a breakdown of the normal synergy of rolling and gliding. This breakdown involves an increased gliding in the normally dominant, rolling phase of the screw-home mechanism. The gliding, combined with increased rolling, causes the femur to roll up onto the posterior horn of the lateral meniscus, and glide back off as the knee goes into flexion. Chronically this condition may lead to meniscal deterioration (Chalandre, 1977; Olsson, 1972). One clinical test for cruciate insufficiency is the pivot shift. First noted by Slocum and Larson (1968), the pivot shift phenomenon illustrates the pathological rotatory freedom prevalent in complex forms of instability. This pivot shift action is actually a lateral tibial plateau subluxation which can cause instability, deterioration of the femoral condyle, and meniscal pathologies (Segal, 1980). The critical role of anterior cruciate insufficiency in eliciting this subluxation was investigated by Jakob and Noesberger (1977) and Galway (1979).

Biomechanically, the femur rolls without gliding up to 30 degrees of flexion, and consequently it is displaced abnormally posterior on the tibial plateau (assisted via the convexity of the lateral tibial plateau). The actual shift is elicited through a strong valgus pressure which favors rolling over gliding when the ilio-tibial band is pulled taut by internal rotation of the tibia. The tract forces the lateral condyle of the femur back until about 30-40 degrees of flexion. At this point it crosses the culmination point of the femoral condyle and the momentary flexion axis. Upon reaching this point the femur is able to return to its normal position. However, as the tibia lies most distally, it is the tibia which actually snaps back into place relative to the femur. The forces applied by the ilio-tibial tract (which are able to do this because of their anatomical structure) enable them to act as both a flexor and an extensor of the knee depending on the flexion angle. The elicitation of the pivot shift is often described by the patient as a period of instability in which he feels the knee "give way" as he pivots. Consequently, a decreased function ability, especially in athletic endeavors, is a major complaint of the ACL deficient patient.

Both the pivot-shift instability (often referred to as anterolateral rotatory instability), and the pure increased anterior translation resulting from ACL deficiency, comprise, in various magnitudes, the functional and physiological degeneration associated with this pathology.

2.2.6. LIGAMENT INTERACTION

The normal knee is stable throughout its range of motion, but the stability is certainly not constant. The coordination of different ligaments' tensile strength varies throughout the range. What may be classified as pathological laxity, may in reality be greater functional potential in the knee at that specific angle; greater functional potential in terms of an increased freedom of movement. The greater functional potential/increased mobility of the flexed knee is controlled by the dynamic stabilizers. Laxity in the "relaxed" knee may disappear once the dynamic stabilizers are brought into play.

In tibial external rotation, the collateral ligaments are more tense, and therefore offer greater resistance to varus or valgus stress than the cruciates (which are lax in external rotation). In internal rotation, the collateral ligaments are lax while the cruciates are entwined with themselves and thus resist varus-valgus stress.

With the close interaction and synergic activity of ligaments, the clinical findings of combination ligament injuries (e.g., PCL with posterolateral collateral, ACL with medial collateral) are expected in proportions as high as 80% (Trillat et al., 1978).

2.2.8. CRUCIATE INTERACTION IN ROTATION

In every cycle of knee flexion/extension there occurs a certain amount of automatic rotation at the beginning of flexion and end of extension (Meyer,1853). Strasser (1917) found that the cruciate ligaments lay in a plane set at a 15 degree angle to the sagittal plane. This shift away from the sagittal plane corresponds to the exact amount of physiological automatic rotation occurring in the last 20 degrees of extension. The rotation appearing in the initial degrees of flexion is the reverse of the terminal extension rotation.

Grigis et. al. (1975) found an average increase in internal rotation of 8 degrees in extension after sectioning of the anterior cruciate ligament (range of 0-15 degrees). This study was done with a knee that had all other ligaments intact, a rare occurrence in real-life situations.

Lipke et. al. (1981) reported a statistically significant increase in internal rotation with isolated ACL section. Even greater increases in internal rotation were observed when secondary structures (the posterolateral complex and lateral collateral ligament) were sectioned. However, when the secondary restraints were sectioned without sectioning of the ACL, no significant increase in internal rotation was observed. The authors concluded that for pathological internal rotation of the tibia on the femur to occur, there must be an insufficiency of the anterior cruciate ligament.

The cruciate ligament arrangement allows for their relaxation during external rotation, and tightening via twisting in internal rotation. Simultaneously, the collaterals work reciprocally by becoming taut in external rotation and lax in internal rotation. Together they define the structural limitations of rotation in the knee joint.

Huson (1974) states that although the cruciates are taut in neutral rotation (full extension), the terminal rotation is allowed because of the posterior inferior slope of the lateral tibial plateau, which provides enough decrease in longitudinal cruciate tension to allow them to coil in rotation. Thus this tension decrease through the shape of the plateau at the end of extension, gives the knee enough freedom of movement to rotate. This rotation winds the ACL and PCL around each other which again increases their tension and helps to restrict A/P motion.

Voluntary rotation at a variety of flexion angles has been investigated by a number of experimenters using a technique of clamping the foot in a neutral position to isolate the ankle joint and rotating the tibia (Reutsch and Morscher, 1977). Although the results are not consistent between authors, the greatest rotation seems to occur at 45 degrees of flexion. Muller (1985) suggests that the amount of rotatory excursion available in voluntary rotation corresponds to the amount of rotatory displacement of the menisci in each flexion angle.

Rotation must be an important aspect for consideration when proceeding with the anterior drawer test. The maintenance of a consistent, measurable degree of rotation is essential, although at times difficult, as the tibia tends to move into internal rotation with an anterior force and to external rotation with a posterior force. This is possibly due to the forces exerted by increasing tension in the ACL. The increased rotatory motion is often misinterpreted as increased tibial translation. Often, in the Lachman's test, a greater anterior displacement occurs on the lateral condyle of the tibia due to its greater rotatory movement.

2.3 EVALUATION OF KNEE LAXITY

Specific knee laxity tests attempt to isolate the major ligaments, and stress them to produce an abnormal movement (indicative of ligament disruption). The abnormal displacement of the knee joint has traditionally been assessed qualitatively. This is a subjective assessment involving both a proprioceptive and visual perception of movement between the two joint surfaces.

Obviously, the accuracy of a visual/proprioceptive technique which measures in units such as millimeters and degrees is questionable. The need for a reliable, valid testing device is undisputed; but, in an attempt to increase accuracy, the critical aspect of "end-feel" (ligament compliance) in the knee ligament exam must not be undermined in its multi-faceted analysis of the structure.

2.3.1. CLINICAL EXAM

Torg et.al. (1976) reviewed the clinical and operative findings of two hundred and fifty knees which came to surgery for "internal derangement". The operative findings were correlated with the classic anterior drawer sign at ninety degrees, the rotatory instability (pivot shift) test described by Slocum, (1968) and the Lachman's test. The knees which had operative findings of isolated meniscal tears had negative findings in all three tests both pre and post-operative. Isolated tears of the anterior cruciate ligament resulted in a positive Lachman's test only. It was then reported that the Lachman's test is the only test specific for a diagnosed disruption of the anterior cruciate ligament. Anterior cruciate disruption was also observed in this study in 79% percent of knees with tears of the medial meniscus suggesting a functional relationship between the two.

A recent investigation by Rosenberg and Rasmussen (1984) further clarified the functional characteristics of the anterior cruciate during clinical testing in vivo. Normal subjects were examined using arthroscopy, and a special probe which was designed to measure tension in the material it contacts. The tip of the probe was calibrated in millimetre increments, and a spring scale mechanism on the handle of the probe allowed the surgeon to apply a known force to the ligament while the amount of displacement (Lachman's) was simultaneously recorded. The ACL was divided arbitrarily into three sections; anteromedial, central and posterolateral. Tension in each segment was evaluated before and during testing with a drawer test performed at ninety and fifteen degrees of flexion. Baseline tension was reported as being consistently greater at fifteen degrees of flexion than at ninety. The Lachman's (at fifteen degrees) produced maximal tension in all sections of the ligament (the posterolateral segment showing slightly less), while the classic anterior drawer at ninety produced a parallel tension increase to a maximal force less than the Lachman's.

This in vivo study, along with that of Torg et.al. (1976), supports the specificity of the Lachman's test as an indicator of anterior cruciate ligament integrity. Once validated in this manner, the quantification of this test must be addressed.

Probably the most accepted scale or classification of degree of instability is the scale devised by Houghston et.al.(1976). He describes three levels of severity in ligament disruption. A first degree tear is defined as a separation in a small number of fibers with localized tenderness but minimal instability. This is manifested by a joint surfaces displacement of 5mm or less. The second degree tear involves a greater number of fibers disrupted, increased generalized tenderness and a displacement of between 5 and 10mm. Finally, a third degree tear refers to complete disruption of the ligament with a joint displacement of over 10mm and a corresponding instability. Houghston admits a lack of objective accuracy in the test, but states that it "provides a workable scale for clinical use". Since the time of the Houghston classification, the subjective measurement has been modified into four grades for the assessment of anterior-posterior translation. Each of the four grades indicates a 5mm increase in translation (Losee 1985).

The anterior-posterior test at 30 degrees of knee flexion which has been incorporated into this study has been scrutinized fairly extensively in the literature. Markolf (1978) examined the Lachman's test by recording anterior-posterior force versus displacement through a test apparatus designed to assess in vivo joints. It was reported that the rate of the force application did not affect the force-displacement curve (0.5 to 1.0 seconds) in repeated measures. Measurements of "stiffness" were taken as the slope of the curve at a force of one hundred newtons. Laxity measurements were also taken at this point. Identical curves of right and left laxity were rare occurrences. Results of the analysis reported equal frequency for the most stable knee to be on either the right or left side. The average absolute values of the right-left difference for the Lachman's was 1.8mm. The Lachman's test also showed the greatest right-left differences. The average anterior-posterior displacement for this test was 5.5 millimeters. Finally, it was of interest to note that the subjects were able to increase their knee stiffness an average of two to four times when asked to tense their muscles.

In a study previously described by Fukubayashi et.al. (1982), it was reported that when rotation is constrained in normal knees, a thirty percent decrease in anterior displacement was observed. This could possibly be explained by the rotational movement being closely linked to the anterior translation such that they occur simultaneously.

In summary, the clinical evaluation of cruciate deficiency has traditionally been measured through the anterior drawer test. This test, called the "Lachman's test" when performed at 30 degrees of flexion, has been shown to be specific to isolated ACL rupture. There has also been reports of variability in the measurement of these cases with changing rotatory positions of the tibia. The wide clinical use along with comparative data was the criteria for the inclusion of this test.

2.3.2. RADIOGRAPHIC TECHNIQUES

There has been a limited amount of data in the last decade attempting to quantify knee laxity with radiographic techniques. Many of the experiments, using this technique to measure laxity, use cadaver specimens which are able to have various hardware pieces inserted into the knee to serve as measurement land marks.

The definition of the landmarks is the most difficult task in objectively measuring off radiographic pictures. Kennedy and Fowler (1971) measured in vivo lateral radiographs; but, they did not define reference points for measuring, therefore the reproducibility of their results is unknown. Jacobson (1976) also described a procedure for measuring anterior-posterior displacement of the tibia on the femur. He used measurement distances, as defined from specific points, in both the medial and lateral femoral condyles. The measurements were made off the films using vernier calipers. An average of the medial and lateral femoral condyle displacements was used to obtain a value for the total displacement in each knee. Results from this study showed that for 50 normal male and female subjects, a 95% confidence interval of 2.4 mm was established with a wide biological variation between subjects. The author disagreed with Kennedy and Fowler (1971) who stated that both medial and lateral condyles displaced an average of 5 mm with anterior traction. Their results showed the medial condyle displacing an average of 5.5mm and the lateral 9mm. Jacobson (1976) claimed that this discrepancy was probably due to confusion regarding the position of the posterior condyles of the tibial condyles which were used as measurement reference points.

2.3.3 INSTRUMENTED DEVICES

The importance of obtaining quantitative data for knee laxity parameters has led to the production of various testing devices. Most of these devices, such as that described by Markolf (1978), are designed for experimental use. However, as clinical studies increase in frequency, and physicians attempt to improve diagnostic accuracy (reliability), the need for an easily applied, objective testing device is apparent. Presently there are two devices which selectively measure anterior-posterior laxity: the Stryker knee laxity tester and the Med metric KT1000 with the Genucom measuring three dimensional tibio-femoral displacement.

The KT1000 Knee Arthrometer measures anterior-posterior tibial excursion relative to the femur at 20 and 90 degrees of knee flexion. The lower limb is positioned by a thigh and a foot rest in a position of constant flexion and tibial rotation. The foot rest provides some constraint to external rotation in the initial position of the tibia, but does not interfere during the test. The device attaches with two velcro straps onto the shaft of the tibia, and has a moveable portion which rests on the patella. Two sensor pads are incorporated into the device; one on the patella and one contacting the tibial tubercle. A measurement of relative motion between the sensor pads is obtained when the examiner applies an anterior-posterior force to the tibia. Prior to measurement, a testing reference position is established as being the resting position of the knee after applying and releasing a 89 N posterior load. A dial gauge registers the displacement, and the amount of force is measured through a force sensing handle located ten centimeters from the joint line. Displacement can be read from the dial to the nearest millimetre.

Daniel et.al. (1985a) investigated this device in three cadaver specimens: three hundred and thirty eight normal subjects, and eighty nine patients with ACL insufficiencies (unilateral). Results from normal in vivo knees exhibited a total A/P displacement at a force of eighty-nine newtons (twenty one pounds). A compliance index was also determined for these subjects as the increase in anterior displacement between sixty-seven and eighty-nine newtons. The bilateral difference in the compliance index was not greater than 0.5 millimeters for ninety-three percent of the normal patients.

Conversely, the mean anterior-posterior displacement in the subjects with anterior cruciate ligament disruption was 13.0 millimeters and the mean difference of the bilateral compliance index was 1.7 +/- 1.1 millimeters. Eighty-five percent of the sample showed a bilateral difference in the compliance index of over 0.5 millimeters. In contrast to the findings of Markolf et. al. (1978), it was observed that ninety two percent of the subjects had an absolute difference between sides of no more than two millimeters; thus appearing to be fairly symmetrical. In the subjects with unilateral ACL deficiencies, ninety six percent had right-left difference of over two millimeters (mean of 5.6 millimeters). This result was consistent with that found by Markolf et.al. (1984) and Shino et. al. (1984), who found mean differences in similar situations of 5.5 millimeters and 5.7 millimeters respectively.

Daniel et.al. (1985b) also reported on the use of the KT1000 for the measurement of patients with acute anterior cruciate ligament disruption. One hundred and thirty subjects were assessed within two weeks of their initial injury. Normal values were established through the evaluation of one hundred and twenty normal subjects. The average tibial displacement at a twenty pound force was 7.2 millimeters with a standard deviation of 1.9 millimeters and a range of 3.0 mm to 13.5 mm. The compliance index (difference between tibial excursion with a fifteen pound force and a twenty pound force) for the normal knees had a mean of 0.9 with a standard deviation of 0.4 and range of 0-2.5. Right-left differences averaged 0.8 millimeters with a compliance index difference average of 0.2 lb/mm. The validity of this device in terms of its ability to measure increased sagittal tibial displacemert in ACL deficient knees was not shown to be statistically significant.

Reliability of this testing device has not been specifically assessed. However, in a sample of 25 normal subjects an average displacement of 7.6 mm (standard deviation= 1.7mm and range=4.0 to 12.0 mm) was reported by Daniel et al. (1985). It is important to consider how the device controls for extraneous variables. The KT1000 deals with the possibility of hamstring tightness through thigh massage and through performing some rapid A/P oscillations on the tibia prior to measurement. Flexion angle is maintained at 30 degrees through the positioning device. External rotation is slightly constrained, but internal rotation is left free. Soft tissue compensation is a problem to be considered in two areas of contact: at the patellar button and at the tibia. At the tibia, soft tissue compensation in the posterior force application is negligible as there is no musculature covering the anteromedial shaft of the bone. Anterior force application is applied through a strap beneath the gastrocnemious muscle group, and soft tissue compression is controlled for when the tissue must be fully compressed before affecting the tibial displacement sensor. At the patella, a manual force is applied throughout the test to compress the patella within the femoral trochlea. As it is difficult to maintain a consistent amount of force at times while simultaneously applying the displacement force, the possibility for error must be taken into account. Also, if the knee is swollen, it is difficult to compress the patella within the trochlea.

A similar device to the KT1000 is the sagittal knee laxity tester manufactured by the Stryker Corporation. This also measures anterior-posterior tibial displacement at 20 to 90 degrees of flexion. The tibia is maintained in a neutral position and the examiner uses a instrumented force applicator to apply a specific amount of force to the tibia in a sagittal plane. The subject is seated on a positioning platform in a relaxed posture of long sitting while both thighs are secured with a velcro strap to avoid rotatory forces. An "aligner device" is then attached to the leg about to be tested by two elastic straps: one at the tibial tubercle and the other at the malleoli. The proximal portion of this alignment device extends to form the patellar button which rests on top of the patella. When positioned correctly, the device is almost in line with the shaft of the tibia except for a distal lateral deviation to account for the quadriceps Q-angle. Translation is measured between the two reference points, patellar button and tibial tubercle of this component, and indicated on a spring-operated scale located on the patellar component. The spring-loaded force applicator has an accuracy indicated to the nearest pound. The available force range is 40 pounds in either direction. Calibration of the force applicator was tested with predetermined weights of 20, 30 and 40 pounds prior to the testing procedures. The measurement scale on the patellar button is in millimeters and is calibrated at the zero position when placed on the patella. As with the KT1000, hamstring relaxation may be facilitated by rapid A/P oscillations and thigh massage. The flexion angle of the knee is obtained using a positioning device which can be adjusted to test at various degrees of flexion. There is, however, no control for either internal or external rotation of the tibia. Soft-tissue compensation at the site of the force application is established in the same manner as described with the KT1000. At the patella, however, a controlled amount of compressive force is obtained through a spring loaded in the patellar button. To date there has been no data published concerning the reliability and validity of this device. The scale is displaced with the A/P applied force, and returns to the initial testing position to leave a measurable displacement reading in millimeters on the scale. The force applicator is also spring operated with a range of 40 pounds in anterior and posterior directions.

The advantages of this device are: 1) Mobility; which allows it to be used in the operating room or in athletic therapy clinics. 2) It is able to provide an easily obtainable objective measurement of knee laxity in the sagittal plane with minimum discomfort to the subject. Alternatively, its disadvantages include: 1) Lack of sufficient rotational constraint of the femur and the tibia, leading to possible variation in measurement. 2) The force handle does not indicate exact measurements, and is difficult to see while force is being applied. 3) Accuracy of the recording component at the patellar button is questionable. To elaborate on the third factor, as the tibia displaces with respect to the femur, the marker on the corresponding A/P scale is displaced simultaneously. When the force is withdrawn the tibia returns to "neutral" and the displacement scale is shown. This device operates on the assumption that the "neutral" position of the tibia is consistent; an assumption which may be questionable if the normal range of tibial translation on the femur is considered. If the tibial position does not return to a consistent neutral position, the displacement reading will not be accurate.

The Genucom device consists of a computerbased system incorporated into a patient testing chair. The system is controlled by a program disk which is run through one of two disk drives located in the base of the machine. The second drive is for patient diskettes which are formatted by the program disk. The patient disk is prepared by creating a file on the patient and listing relevant identification information. There is a 6 component force dynamometer built into the chair to measure forces and calculate moments applied to the knee. A six degree of freedom goniometer is attached to the tibia in order to measure the joint angle and tibial / femoral displacements. This device has a documented accuracy of +/- 1mm translation on sliding displacements, +/- 1 degree on rotational measurements and +/- 4.455 N on applied forces as measured via the dynamometer (Raab and Fraser, unpublished). Three-dimensional knee position is initially recorded through digitization of specific bony landmarks surrounding the knee. A point digitizing attachment is mounted onto the electrogoniometer and can be used to locate spacial points. This information is recorded onto the patient diskette and the goniometer subsequently attached to the distal end of the tibia where, on displacement, it records knee position based on the digitized coordinates. Force is recorded simultaneously with displacement through the dynamometer.

The subject is initially installed into the device; a process which involves stabilizing the trunk with a velcro strap at the waist, resisting the greater trochanter area of each hip, and buttressing the femur. The femur is buttressed in four directions: anterior-posterior and medial-lateral. After the installation, the program goes into a procedure for soft tissue compensation. Tissue deformation is compensated for in six directions: anterior-posterior, medial-lateral, and superior-inferior. This compensation is measured by a sequence of hand-applied forces (in the range of 112 to 156 Newtons) on the distal end of the femur. Once this compensation has been established, the operator then proceeds with the specific tests desired.

Tests which are included in the evaluation procedure consist of: the anterior-posterior drawer test, the dual anterior-posterior drawer test, the internal- external rotational stress test, the varus-valgus stress test, the genu recurvatum/screw-home test, and the pivot shift test. The advantages of the Genucom system include: 1. the simultaneous measurement of sagittal displacement in the frontal plane, axial rotation, frontal displacement in the sagittal plane and knee flexion angle at any desired degree. 2. force can be measured in six directions throughout the test (an important factor in controlling extraneous variables which may influence displacement). 3. force is plotted against displacement giving a continuous data recording for evaluation. Disadvantages include the initial cost of the machine, the fact that the machine is non-mobile, and the experience required to accurately perform the tests. Reliability data for the Genucom is addressed in the present study.

Evaluation of knee joint biomechanics is a complex area as is reflected in the quantity of literature relating to this topic. The cruciate ligaments are involved in the control of a variety of three-dimensional physiological movements throughout the normal range of motion. This complexity and inter-relationship of the cruciates with many other mobile and static structures is of principle consideration in the assessment of cruciate function and integrity.

CHAPTER III

METHODS AND PROCEDURES

The goals of this study were to investigate: 1. whether the three instrumented devices, KT1000, Stryker, and Genucom, were reliable in repeated measures on a single subject. 2. whether there was a significant difference between tests of A/P laxity at thirty degrees of flexion between the five measurement procedures (Clinical examination, X-ray, KT1000, Stryker and Genucom), and 3. to describe the variance characteristics of the three devices over a number of trials.

These goals were addressed through a two part design. The first part concentrated on characterizing the variation of the three devices (KT1000, Stryker and Genucom) over a two day time frame using a single subject and a group of ten normal subjects. This data was collected and a two-factor ANOVA with post-hoc comparisons was employed to assess the variance characteristics of each device. The second part of the study involved a similar ANOVA design but incorporated additional factors, the clinical and X-ray devices to test against accepted diagnostic procedures, and both normal and cruciate deficient knees to test the clinical ability of the measurement procedures to distinguish between the two populations.

3.1 SUBJECTS

In the first part of the study, ten male subjects were assessed. One of the subjects was measured ten times on each device for the two days and the other nine had three scores taken with the average of these used in the analysis. All of the subjects were between the ages of 22 and 25 years with no history of knee injury or pathology.

In the second part of the study, fifteen male subjects between the ages of 18 and 26 years with unilateral chronic anterior-posterior laxity were evaluated. The subjects were referred from the practice of a local orthopaedic surgeon. Subjects were excluded on the basis of having: a) severe functional disability with normal daily activity, b) severe structural abnormality of the knee and/or c) recent knee injury with effusion. This data was obtained from the clinical records of the patient along with a patient information questionnaire (Appendix II).

Both the left and right knees of each subject were tested. The order of testing was balanced to minimize possible effect of testing order. In order to decrease variance due to gender, the population was restricted to males.

3.2 DESCRIPTION OF THE STUDY

The present study incorporated two parts. The first part of the study involved an individual assessment of the reliability and validity of the three mechanical devices while the second part investigated the relationships between the five measurement procedures. Both parts involved a factorial design.

3.2.1. Part 1

In the first part of this investigation, the three mechanical devices, the KT1000, the Stryker, and the Genucom were evaluated separately on a single subject and ten normal subjects (Table 1). This was done in order to assess reliability for the device-operator combination. Day 1 / Day 2 reliability was described through a 2 factor ANOVA design, one factor being DEVICE which included each of the mechanical devices and the other factor being DAY, (Day 1 - Day 2).

3.2.2. Part II

Two two-factor ANOVA designs were included in the second part of the experiment (Table 1). The first factor, A, remained constant over both ANOVA's and was defined as the procedure used for laxity measurement. Five levels of factor A were included: 1. the radiographic stress test, 2. the clinical evaluation, 3. the Genucom assessment, 4. the KT1000 procedure, and 5. the Stryker procedure. The second factor, B, consisted of the knee population, cruciate deficient and normal.

TABLE 1: DESIGN MATRICES

PART I: MEASUREMENT TECHNIQUE BY DAY

FACTOR B: DAY

FACTOR A: DEVICE

	GENUCOM	KT1000	STRYKER
DAY 1			
DAY 2			

PART II: MEASUREMENT TECHNIQUE BY KNEE

FACTOR A: MEASUREMENT TECHNIQUE

FACTOR B: KNEE

	CLINICAL	STRYKER	KT1000	GENUCOM	XRAY
INJURED					
UNINJURED					

The dependant variable in both parts of this design was the measurement of tibial displacement relative to the femur in the sagittal plane.

In part II five measurements were collected on each subject for each level of the independent variable except for the radiographic and clinical measurements. The average of the five scores was recorded as the subject's true score.

Data for each of the evaluations was recorded on separate data collection sheets in order to ensure that the examiner was not aware of the other scores of the individual.

3.3 EVALUATION METHODOLOGY

3.3.1. CLINICAL TEST

In the clinical test, commonly recognized as the Lachman's test, the tibia was maintained in a neutral position. Both knees were evaluated at a thirty degree flexion angle. The laxity was graded according to a modified scale of the one used by Houghston and others (1976) and was recorded by the physician (Appendix III). For the purposes of statistical analysis, the Houghston scale was employed with the addition of an initial level of 0 to describe no observable displacement.

3.3.2. GENUCOM TEST

The Genucom testing device is a computer-based instrument which consists of an evaluation chair with an attached computer terminal. Within the chair is a 6 component force dynamometer and a 6 degree of freedom electro- goniometer which attaches to the patient's tibia to measure tibial movement relative to the femur.

The patient was "installed" into the machine in a procedure which stabilizes the trunk, hip and femur. A soft tissue compensation procedure was then completed to ensure that true tibial motion relative to the femur was being measured, and not displacement of the surrounding soft tissue.

Prior to attaching the tibial goniometer holder, the following landmarks were digitized with the goniometer: mid points of the tibial tubercle, medial tibial condyle, lateral tibial condyle, and the anterior midpoints of the medial and lateral femoral condyles. The anterior drawer test was performed at 30 degrees of flexion. Three tests were done on each subject with the average taken as the subject's score.

3.3.3.STRYKER KNEE LAXITY TESTER

The Stryker Knee Laxity Tester consists of three components: one designed for the application of an appropriate force on to the tibia, one for the measurement of tibial translation relative to the femur, and a component to secure the lower limb and position the flexion angle of the knee. The force applicator quantified the amount of force applied through a spring and corresponding force scale. The component designed to measure tibial translation consisted of a plunger with a "button" which rests on the patella and is attached to a metal rod. This metal rod was secured to the lower leg by two circumferential elastic straps. The first strap was positioned distally, five centimeters proximal to the malleoli of the tibia, and the second strap at the tibial tubercle. Care was taken to properly secure the proximal strap, as translation was measured relative to this landmark at the tibial tubercle.

The Stryker testing device was operated according to the the following procedure. The subject was seated on an examination table in a position of long sitting to relax the hamstring and quadriceps muscles. Both of the lower limbs were positioned on the device at a 30 degree flexion angle. A velcro strap secured the lower end of each femur a distance of approximately ten centimeters from the tip of the patella. The lower leg rested on a padded bar which did not constrict tibial rotation in either direction. The spring operated force applicator was used to apply a perpendicular anterior-posterior force at a distance of ten centimeters distal to the joint line.

3.3.4. THE KT1000 KNEE ARTHROMETER

The KT1000 knee arthrometer is a self contained device which attaches to the anterior aspect of the tibia (Figure 2). A thigh support and foot support are also supplied with the device to aid in positioning the limb for testing. These supports do not restrict internal rotation of the tibia; however, the lateral aspect of the foot support offers some restriction to external rotation of the tibia.

The arthrometer itself was fastened onto the tibia with two velcro straps. Within the device, two sensor pads at the patella and at the tibial tubercle indicated relative displacement in the

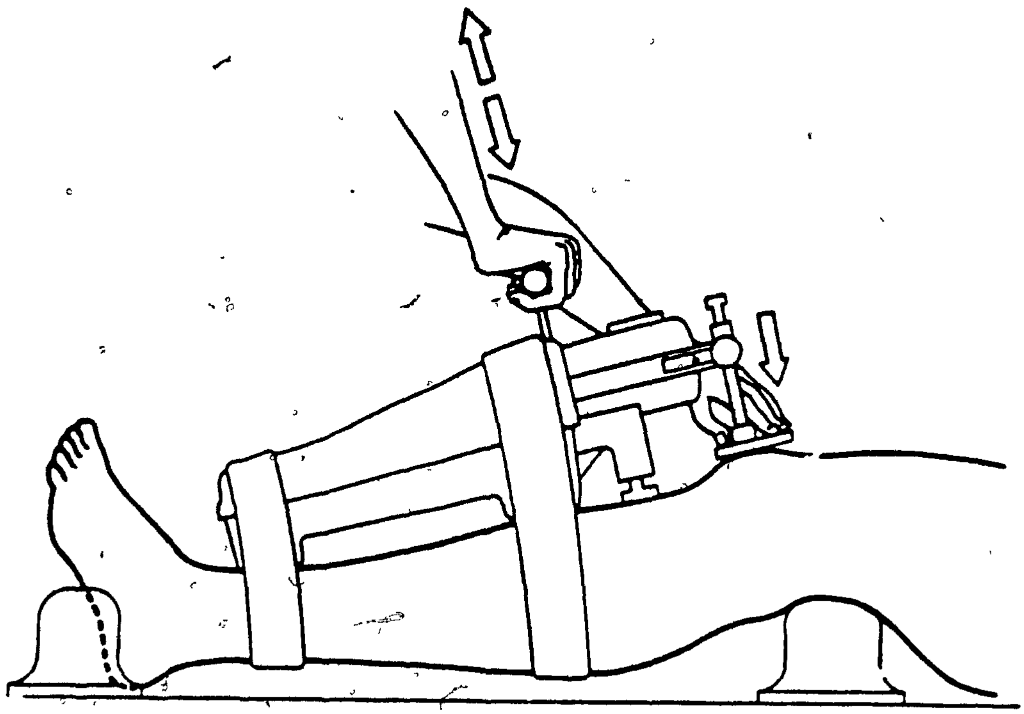

Figure 2. The KT1000 Knee Arthrometer

anterior-posterior direction. Displacement force was applied through a force-indicating handle located ten centimeters distal to the joint line. An audiotone signaled at force applications of fifteen pounds (67 newton) and twenty pounds (89 newton) in both anterior and posterior directions. Pressure was applied to the patellar sensor pad to stabilize the patella in the trochlea of the femur. A constant firm pressure was applied throughout the test. Initially, a reference point was found by repeatedly applying posterior force until a reproducible, unloaded knee position was found. The instrument dial was then set at zero, and anterior and posterior forces applied. Displacement was recorded from the dial on the arthrometer.

Each of these pieces of equipment were designed to measure horizontal displacement in the sagittal plane between the tibia and femur.

3.3.5. RADIOGRAPHIC MEASUREMENT

Each subject was evaluated bilaterally through stress radiographs. The subject was seated in long sitting with the leg (knee) to be tested secured in a position of 30 degrees of flexion, with the femur clamped in the A/P and medial-lateral directions. The ankle was loosely strapped into a neutral rotation position. A velcro strap was fastened securely onto the tibia approximately ten centimeters from the joint line. This strap had a cord attached to it which was aligned perpendicular to the shaft of the tibia and clamped in place. Tension was applied on this cord with a strain gauge measuring force to a value of twenty pounds just prior to x-ray film exposure. The X-ray film cassette was positioned parallel to the sagittal axis of the knee joint directly against the lateral joint line. The x-ray beam was coned in from the medial-lateral direction and the picture taken. The procedure was then repeated for the alternate knee. Superimposition of the two femoral condyles was established for each picture in order to standardize the amount of femoral rotation which could interfere with measurement accuracy of anterior-translation. Two radiographs were taken of each knee; one with an anterior force of twenty pounds applied, and one with a posterior force of twenty pounds applied. Measurement of total displacement in the anterior-posterior direction was done by superimposing the two films on each other, alignment of the femoral condyles, and measuring, with vernier calipers, the total tibial displacement from the most anterior position of the tibial tubercle.

3.4 DATA COLLECTION AND ANALYSIS

In Part I, the analysis of the single subject / day1, day2 data was done using a 2-way ANOVA. This was followed by post-hoc comparisons in which a Scheffe test was incorporated to control for experimentwise error. The ten subject / day1, day2 group of data was also treated with the same method of analysis. The single subject analysis was done in order to investigate the device-operator reliability. The ten subject group was added to further aid in its clinical applicability and strengthen the application of the data collected in the second part of the study.

The analysis of Part II also consisted of a two way ANOVA followed by post-hoc tests to locate the source of variance. An alpha level of 0.05 was utilized throughout the statistical analysis.

All of the statistical analysis was done using the SPSSX:2.1 program on the MUSIC (McGill University System of Interactive Computing) system.

TABLE 1: DESIGN MATRICES

PART I: MEASUREMENT TECHNIQUE BY DAY

FACTOR B: DAY

FACTOR A: DEVICE

	GENUCOM	KT1000	STRYKER
DAY 1			
DAY 2			

PART II: MEASUREMENT TECHNIQUE BY KNEE

FACTOR A: MEASUREMENT TECHNIQUE

FACTOR B: KNEE

	CLINICAL	STRYKER	KT1000	GENUCOM	XRAY
INJURED					
UNINJURED					

The dependant variable in both parts of this design was the measurement of tibial displacement relative to the femur in the sagittal plane.

CHAPTER FOUR

ANALYSIS AND RESULTS

The study was designed to make a comparison between the following knee laxity devices, Genucom, KT1000, Stryker on the basis of anterior-posterior translation measurement (in millimeters) in the sagittal plane. This chapter includes sections concerning: 1. subject description and characteristics, 2. results of Part I: reliability measurements for the Genucom, KT1000 and the Stryker laxity testing devices and 3. results of Part II, the analysis of variance between the two independent variables: knee populations (normal and cruciate deficient knees) and the five measurement procedures.

4.1 SUBJECT CHARACTERISTICS: PART I AND PART II

In the first part of this study which investigated the reliability of the Genucom, KT1000, and Stryker devices, ten subjects (none of whom had a history of knee pathology) were used in each of the repeated evaluations. These subjects were of similar muscular morphology. This similarity in muscular development refers to a minimal amount of adipose soft tissue surrounding the knee joint, and is important in minimizing the error created by excess soft tissue surrounding the bony prominances. Prior to initiating the testing sequence, the subjects were instructed in a sequence of stretches for the hamstring muscles in order to minimize variation due to muscle stiffness.

A total of fifteen subjects were tested in the second part of the investigation. Fourteen of these subjects had unilateral cruciate ligament deficiency, one bilateral cruciate ligament deficiency, one posterior cruciate deficiency, and one with no documented pathology. A total of fifteen normal and fifteen cruciate deficient knees were assessed. The subjects were all requested to fill out a patient information form in order to provide a more detailed description of their pathological history (Appendix II) . The information collected from these questionnaires is summarized in Table 2.

TABLE 2

SUBJECT INFORMATION SUMMARY

SUBJECT	AGE	INITIAL INJURY	SURGERY	MENISCUS	ACL	PCL
1.	23	NOV. 1981	SCOPE	X	X	
2.	21	OCTOBER 1983	REPAIR	X	X	
3.	25	OCTOBER 1982	REPAIR	X	X	
4.	24	APRIL 1986	SCOPE		X	
5.	25	NOVEMBER 1980	SCOPE	X	X	
6.	21	JANUARY 1981	-		X	
7.	24	NOVEMBER 1978	SCOPE	X	X	
8.	27	SEPTEMBER 1982	-		X	
9.	26	MAY 1982	SCOPE	X	X	
10.	22	MARCH 1985	SCOPE	X	X	
11.	20	SEPT 7 1985	REPAIR		X	
12.	25	AUGUST 1982	SCOPE	X	X	
13.	28	JULY 1980	SCOPE	X	X	
14.	28	MARCH 1980	SCOPE	X	X	
		JULY 1983	REPAIR	X		X

The sample population consisted of fourteen anterior cruciate deficient knees, and one posterior cruciate deficient subject. The majority of the subjects had some associated meniscal pathology (eleven out of fifteen). The subjects were homogeneous in age, ranging from 20 to 28 years. The length of time from the initial injury until testing ranged from three months to eight years. Most of the injured knees had undergone arthroscopic surgery (thirteen of fifteen), and four of the fifteen had undergone a ligament repair procedure.

4.2 PART I: RELIABILITY DATA ANALYSIS

The analysis of data collected with each of the three instrumented devices was an important pilot study prior to the evaluation of the five measurement procedures in order to increase the clinical application of the results. A single subject was tested with each device 10 times for two subsequent days. Ten normal subjects were also tested on each of the devices for two subsequent days. This design was used in order to: 1. measure variation due to normal day to day knee laxity (single subject) and 2. measure variation in a normal population over a two day period.

4.2.1. STATISTICAL DESCRIPTION OF THE VARIABLES

As can be noted in Table 3, the descriptive statistics for both the single subject and ten subject reliability data are quite similar; although, as expected, the variance and standard deviation is much greater in the ten subject values. The ten subject design treated each knee as a separate entity, thus increasing the subject number to twenty. This was done as the right -left differential was not being addressed in this section.

TABLE 3A

DESCRIPTIVE STATISTICS: PART I RELIABILITY DATA (millimeters)

SINGLE SUBJECT	GENUCOM			KT1000			STRYKER		
DAY 1	MEAN	STD	VAR	MEAN	STD	VAR	MEAN	STD	VAR
RT.KNEE	6.8	.789	.622	4.8	1.03	1.07	4.3	.675	.456
LT.KNEE	7.1	.876	.769	4.8	.42	.178	4.6	1.07	1.16
DAY 2									
RT.KNEE	7.3	.675	.456	5.7	.675	.456	5.1	.876	.767
LT.KNEE	6.7	.823	.678	4.4	.516	.267	4.2	.422	.178
TEN SUBJECT									
DAY 1	7.75	2.17	4.72	6.8	1.54	2.38	6.8	1.51	2.27
DAY 2	7.8	2.44	5.96	7.0	1.45	2.11	6.8	1.40	1.96

TABLE 3B

PEARSON PRODUCT MOMENT CORRELATION

	R-VALUE (ALPHA=0.05)	R
GENUCOM DAY1 WITH GENUCOM DAY2	.73	.53
KT1000 DAY1 WITH KT1000 DAY2	.78	.61
STRYKER DAY1 WITH STRYKER DAY2	.75	.56

4.2.2. ANOVA RESULTS: RELIABILITY DATA

Tables 4 and 5 indicate the ANOVA Summary tables for single and multiple subject day1 day2 reliability data.

Table 4 shows that there are significant F ratios across the factor DEVICE (Genucom, KT1000, and Stryker), but not across the factor of DAY. This finding led to post-hoc orthogonal comparisons between devices. These comparisons indicated that the devices which had significant score differences were: 1. the Genucom with the KT1000 and 2. the Genucom with the Stryker. This was further verified with a Scheffe test corrected for experimentwise error.

The ten subject analysis summary in Table 5 also indicates a significant F ratio over device, but not over day. Post hoc comparisons indicated similar results to the single subject analysis in that the devices showing significant differences in scores were: 1. the Genucom and the KT1000 and 2. the Genucom and the Stryker. These were also confirmed through post-hoc Scheffe tests. Pearson Product Moment Correlations for the data on two subsequent days showed high correlations for all three devices. The Genucom had an r value of 0.73, the Kt1000 an r value of 0.78 and the Stryker an r value of 0.75 (alpha = 0.05).

TABLE 4

ANOVA SUMMARY TABLE:DAY1 DAY2 SINGLE SUBJECT

Source of Variation	SS	DF	MS	F	SIG F
Main Effects	137.150	3	45.71	66.3	0.000
DAY	0.833	1	0.83	1.209	0.274
DEVICE	136.317	2	68.16	98.856	0.000
2-Way Interactions DAY DEVICE	0.217	2	0.108	0.157	0.855
Explained	137.367	5	27.473	39.847	0.000
Residual	78.600	114	0.689		
Total	215.967	119	1.815		

POST HOC COMPARISONS

		T-Value	Scheffe Range Value
DEVICES	* 1. GENUCOM WITH KT1000	-11.04	3.51
	* 2. GENUCOM WITH STRYKER	-13.22	
	3. KT1000 WITH STRYKER	2.18	

* denotes a significant difference as determined by the Scheffe value (ALPHA=0.05)

TABLE 5

ANOVA SUMMARY TABLE:DAY 1 DAY 2 TEN SUBJECT

Source of Variation	SS	DF	MS	F	SIG F
Main Effects	22.058	3	7.353	2.25	0.08
DAY	0.008	1	0.008	0.003	0.96
DEVICE	22.050	2	11.025	3.385	0.03
2-Way Interactions					
DAY-DEVICE	0.007	2	0.008	0.003	0.99
Explained	22.075	5	4.415	1.356	0.24
Residual	371.250	114	3.257		
Total	393.325	119			

POST HOC COMPARISONS

		T-Value	Scheffe Range Value
DEVICES	* 1.GENUCOM WITH KT1000		3.51
	* 2.GENUCOM WITH STRYKER		
	3.KT1000 WITH STRYKER		

* denotes a significant difference as determined by the Scheffe value (alpha= 0.05)

4.3 PART II; MULTIPLE DEVICE, NORMAL/ABNORMAL KNEES

4.3.1. ANOVA RESULTS:PART II

An ANOVA was performed on the dependant variables to test for any significant differences between the levels of each independent variable: the five testing procedures, and the normal and cruciate deficient knees. Table 6 provides a summary table of the ANOVA including the sums of squares, mean squares, F-ratio and significance of the F value. The omnibus, or overall F-ratio, was significant (alpha= 0.05) in this analysis- leading to a further statistical investigation as to the location of the source of variance. Separate Oneway ANOVA procedures, for each level of the knee population independent variable, were performed followed by planned comparisons among the test procedures for each significant ANOVA.

TABLE 6A

ANOVA SUMMARY TABLE:PART II

Source	Sums of squares	df	Mean Squares	F	Sign. of F
Main Effects	9080.53	5	1816.10	261.69	.000
Knee	4152.89	1	4152.89	598.42	.000
Measure	4927.64	4	1231.91	177.51	.000
2-Way Interactions					
Knee X Measure	360.56	4	90.13	12.99	.000
Explained	9441.09	9	1049.01	151.158	.000
Residual	4788.47	690	6.94		
Total	14229.56	699	20.36		

TABLE 6B

MEASUREMENT PROCEDURE MEAN SCORES (millimeters)

	X-Ray	Clinical	Genucom	KT1000	STRYKER
KNEE					
Normal	2.50	3.07	10.46	6.93	6.67
Cruciate Deficient	6.29	10.71	14.34	11.11	11.53
Difference	3.79	7.64	3.88	4.18	4.86

The Summary table for the ANOVA analysis indicates that the F ratio was significant across both of the factors evaluated. This leads us to further investigate the data in terms of locating the major sources of variance. This was done by analyzing the main effects of each level for each independent variable.

The main effects of the knee population variable showed grand means for the normal and cruciate deficient knees of 6.13 (3.60 SD) millimeters and 11.02 (3.99 SD) millimeters respectively (Table 7).

As there was a substantial main effect across the knee population factor, the measurement procedure factor was further investigated with two separate oneway analyses for each level of knee population.

The first oneway analysis (Table 8) again revealed an F ratio which was significant. Subsequent contrasts between the levels of the measurement factor (Table 8) indicated all contrasts to be significant (alpha -0.05), except for the comparison of the Genucom with the Stryker. The experimentwise error was corrected for using a Scheffe test.

Table 9 illustrates the results from the second oneway ANOVA of cruciate deficient knee population across levels of the measurement procedure variable. This analysis, similar to the first oneway, shows a significant F-ratio. Subsequent contrasts between the levels of measurement showed seven significant T-statistics. These significant T-tests (alpha >0.05) include all except the comparison between the KT1000 scores with the Stryker scores, the comparison of the clinical with the Stryker scores and the comparison of the clinical with the KT1000 scores.

TABLE 7

DESCRIPTIVE STATISTICS PART II (millimeters)

NORMAL KNEES

TEST	N	MEAN	STD	STE	MIN	MAX	95% C.I
XRAY	70	2.64	2.30	.28	0	8	2.1-3.2
CLINICAI	70	3.5	2.7	.32	0	10	2.9-4.0
GENUCOM	70	10.23	3.00	.36	5	16	9.5-11.0
KT1000	70	7.10	1.22	.15	5	11	6.8-7.4
STRYKER	70	7.13	2.07	.25	3	13	6.6-7.6
TOTAL	350	6.13	3.62	.19	0	16	5.75-6.5

CRUCIATE INSUFFICIENT KNEES

TEST	N	MEAN	STD	STE	MIN	MAX	95% C.I.
XRAY	30	6.5	2.8	.36	3	13	5.8-7.2
CLINICAL	30	11.25	3.0	.39	7	17	10.5-12.0
GENUCOM	60	14.68	3.90	.51	8	24	13.7-15.7
KT1000	60	11.20	1.31	.17	9	15	10.9-11.5
STRYKER	60	11.45	3.39	.44	6	20	10.6-12.3
TOTAL	300	11.02	3.99	.23	3	24	10.56-11.47

STD = STANDARD DEVIATION
STE = STANDARD ERROR 95% C.I. = 95% CONFIDENCE INTERVAL

TABLE 8

ONEWAY ANOVA:

NORMAL KNEES WITH MEASUREMENT PROCEDURE

Source	df	Sum of Squares	Mean Squares	F	F Prob.
Between Groups	4	2663.38	665.85	120.71	.000
Within Groups	345	1903.86	5.516		
Total	349	4566.47			

TABLE 9

ONEWAY ANOVA:

CRUCIATE DEFICIENT KNEES WITH MEASUREMENT PROCEDURE

Source	df	Sum of Squares	Mean Squares	F	F Prob.
Between Groups	4	2047.23	511.81	55.6	.000
Within Groups	295	2715.68	9.21		
Total	299	4762.92			

TABLE 10

ONE WAY ANOVA: NORMAL KNEE POPULATION

PLANNED COMPARISON RESULTS

COMPARISON	VALUE	S.ERR	T VALUE	DF	T PROB.
XRAY WITH CLINICAL	-.857	.42	-2.03	135	.045
XRAY WITH GENUCOM	-7.61	.46	-16.67	128	.000
XRAY WITH KT1000	-4.46	.31	-14.31	104	.000
XRAY WITH STRYKER	-4.49	.37	-12.12	137	.000
CLINIC WITH GENUCOM	-6.76	.49	-13.91	136	.000
CLINIC WITH KT1000	-3.60	.35	-10.22	96	.000
CLINIC WITH STRYKER	-3.63	.41	-8.95	130	.000
GENUCOM WITH KT1000	3.16	.39	8.05	91	.000
GENUCOM WITH STRYKER	3.13	.44	7.10	122	.000
KT1000 WITH STRYKER	-0.03	.29	-0.10	112	.921*
CRUCIATE INSUFFICIENT KNEES					
XRAY WITH CLINICAL	-4.75	.53	-8.95	118	.000
XRAY WITH GENUCOM	-8.18	.63	-12.99	106	.000
XRAY WITH KT10000	-4.70	.40	-11.75	84	.000
XRAY WITH STRYKER	-4.95	.57	-8.71	114	.000
CLINIC WITH GENUCOM	-3.43	.64	-5.33	110	.000
CLINIC WITH KT1000	0.05	.42	0.12	81	.906*
CLINIC WITH STRYKER	-0.20	.58	-0.34	116	.733*
GENUCOM WITH KT1000	3.48	.54	6.43	72	.000
GENUCOM WITH STRYKER	3.23	.68	4.78	115	.000
KT1000 WITH STRYKER	-.25	.47	-0.53	76	.596*

* INDICATES VALUES NOT SIGNIFICANTLY DIFFERENT
AS CORRECTED WITH SCHEFFE TEST

CHAPTER FIVE

DISCUSSION OF RESULTS

The purpose of this investigation was to examine the reliability and validity of the various testing procedures for anterior-posterior displacement in normal and cruciate deficient knees. This chapter will focus on the discussion of procedures and results of this investigation with the following topics of concentration: 1. A discussion of the results of Part I of this investigation, reliability of the three mechanical testing devices (including specific reference to single subject results, multiple subject results and discussion of the first hypothesis), 2. Part II hypotheses and results, 3. comparison of results to current research in the area 4. interpretation of statistical results, and 5. clinical and experimental application of results.

5.1. PART 1; RELIABILITY OF TESTING DEVICES

The reliability of the three testing devices was examined through ANOVA evaluations of a single subject, and with a group of 10 subjects in a two day trial. The use of both a single subject and ten subject data collection was to establish both adequate reproducibility of the examiner, (single subject) and appropriate generalizability (ten subjects). Both the single and the ten subject group showed no significant difference in the factor of DAY; their scores on two successive days revealed no significant variation. This would seem to indicate that the score on each device for a single knee is fairly constant across a 24 hour time period given the constraints of the experiment. Across the factor of DEVICE however, both groups tested showed that the Genucom scores differed significantly from the scores of the KT1000 and the Stryker. This would appear predictable given the differences in displacement measurement techniques involved in the Genucom apparatus. The Kt1000 and the Stryker showed no significant differences in scores. It is important to consider the sample population in the interpretation of the data especially in light of the variability involved in pathological conditions of the knee.

5.1.1 HYPOTHESIS I

The first hypothesis stated: There will be no significant difference in the mean scores taken on a single subject and a group of ten subjects in two consecutive days of testing. This hypothesis was accepted (alpha= 0.05) based on the statistical results shown in Tables 4 and 5 of Chapter 4.

5.2. PART 2; HYPOTHESES AND RESULTS

In Part II of the experiment, the group was increased to include five laxity measurement procedures along with both normal and cruciate deficient knees. This was done to test the validity of the devices against known test procedures, 1. the clinical exam and 2. the x-ray procedure which affords a direct measurement of bony displacement. The clinical test was included due to it's frequency of application in everyday practice while the radiographic test was included for it's ability to provide direct visualization of tibial displacement with force application. The most significant aspect of this validity testing is the ability of the devices to differentiate between normal and cruciate deficient knees. A comparison of the absolute measurements was also done as this is an experimentally important factor when dealing with quantitative results. Results from the ANOVA indicate significant variance in both factors, Knee and Measurement procedure. This leads to a discussion of the second and third hypotheses.

5.2.1. HYPOTHESIS II

There will be no significant difference between the measurements obtained by the Genucom, Stryker, KT1000, radiographic and Lachman's tests.

Table 6 shows that there was indeed a significant difference in the average measurements obtained by the various test procedures.

5.2.2. HYPOTHESIS III

There will be no significant simple main effect between the injured and uninjured knees.

Table 6 also indicated a significant simple main effect across the knee population variable; thus leading to further investigation with ANOVA analysis and comparisons. The oneway ANOVA across the population of normal knees (Table 8) showed again a significant F value. Levels of the measurement factor were contrasted and all contrasts were found to be significant (alpha= 0.05) except for the comparisons of scores between the KT1000 and the Stryker. A Scheffe test corrected for experimentwise error. Results of the oneway analysis and post-hoc comparisons with the population of cruciate deficient knees also indicated overall significance and significance, in all contrasts except the contrast between the KT1000 and Stryker scores. A comparison of variance around the mean for each of the devices (Table 7) revealed that the Genucom scores had the greatest variance while the KT1000 scores had the least variance.

5.3. COMPARISON OF RESULTS WITH OTHER RESEARCH

In this, as in any experimental situation, it is important to compare and contrast the results with those reported by other researchers. Instrumented testing of knee laxity is a fairly new technique; therefore, there is not an abundance of literature published in this area. However, there have been some investigations worthy of mention for their comparative value to the present study: Daniel et.al. (1985) concerning measures with the KT1000, Oliver and Raab (1984) for their work with the Genucom and Jacobson (1976) concerning radiographic measurements. This section presents some of the comparative data, and discusses certain similarities and differences.

5.3.1. KT1000 KNEE ARTHROMETER RELATED RESEARCH

Instrumented measurement of sagittal knee laxity using the

KT1000 Knee Arthrometer has been investigated most recently by Daniel et al. (1985). With both cadaver and in vivo specimens tested, mean values were reported in populations of normal and anterior cruciate deficient knees. A sample of 338 normal, in vivo knees (measured at twenty +/- five degrees of flexion) were reported to have an average measurement value of 8.4 +/- 2.2 mm with a range of three to seven millimeters. Comparatively, the results of the present study reported a slightly lower mean value (7.10 +/- 1.22 mm) with a smaller sample of fifteen subjects (five scores on each subject). Daniel (1985) also found that the population of cruciate deficient knees which were tested showed an average score of 15.6 mm. This can be compared with the value of 11.20 mm found in the present investigation. The differences in these scores may be attributed to: 1. the smaller size of sample population in the present study, 2. the normally high variance in individual laxity seen in any given population, both normal and cruciate deficient and 3. the difference in knee joint flexion angle of ten degrees between the two studies.

In another publication by Daniel et.al. (1985b), the average displacement value for a sample of 11 males at a flexion angle of 30 degrees was 7.2 +/- 1.9 mm. This is very close to the value reported in this investigation and could possibly be due to the similarity in flexion angle (thirty degrees).

5.3.2. STRYKER KNEE LAXITY TESTER RELATED RESEARCH

Clinical testing with the Stryker knee ligament tester was described in a report by Steiner et. al. (1986). This study considered anterior-posterior laxity values at 20 degrees flexion for subjects before and after exercising. In their research they also evaluated the test-retest reliability of the Stryker device in their control group of sedentary individuals (n=18). Their test-retest variability showed that 78% of the subjects had a test difference of 0-1 mm, 11% of the subjects had a difference of 1-2 mm, and 11% a variance greater than 2 mm. Corresponding calculations with our test-retest statistics for the Stryker showed that repeat scores between two days of testing for both one subject and a group of ten subjects were not significantly different.

5.3.3 GENUCOM RELATED RESEARCH

Most of the preliminary reports regarding reliability and measurement characteristics of the Genucom involve measurements on cadaver specimens which are not particularly appropriate for comparison with in vivo data. However, there have been some recent communications regarding in vivo analyses with the Genucom.

The reliability of the Genucom was recently investigated by Highenboten (1986). A sample of twenty males (40 knees) showed test-retest correlations of between r= .70 and r= .90. T-tests showed no significant differences between trials for the anterior drawer test at various flexion angles.

These results are similar to those found in the present investigation of repeated A/P drawer at thirty degrees which also show no significant difference in single subject repeated or ten subject scores on two consecutive days; also the test-retest correlations were similar at a value of r = .73 (Table 3B).

5.3.4. CLINICAL TESTING

The Lachman's test has been shown to be a valid indicator of cruciate insufficiency by a number of authors (Torg et.al. 1976, Rosenberg and Rasmusson 1984). It is difficult (although clinically relevant) to try and correlate the Lachman's with the three devices; as many examiners rely on much subjective judgement as well as other clinical signs in the diagnosis of cruciate insufficiency. As the Lachman's test is one of the most widely used clinical tests for cruciate deficiency, it was included in this study as a comparative measure.

5.3.5. RADIOGRAPHIC TEST PROCEDURES

Stress radiography of the knee joint for the detection of pathological laxity has been approached in a number of investigations (Kennedy and Fowler 1975, Torzilli et.al. 1984). Most of these studies involve the anterior-posterior drawer at 90 degrees with the patient in a seated position. Unfortunately, the measurements from these experiments are not applicable to comparison with the present results as the flexion angle differs substantially. There has been some in vitro investigation of anterior-posterior laxity of flexion angles less than ninety degrees. It is felt, however, that comparison of the in vitro data to the in vivo measurements is not accurate due to viscous and muscular changes inherent in the two preparations. Jacobson (1976) reported anterior-posterior displacement measurement via radiographic measurement of the two femoral condyles. The wide biological variation among subjects' knees was emphasized along with the importance of comparing the alternate knee when diagnosing pathological laxity. Results of the present study indicate that the scores are significantly different between normal and cruciate deficient knees even given the wide variation in normal scores.

5.4. VARIABILITY IN PROCEDURE SCORES

5.4.1. INSTRUMENTED DEVICES

The repeated measures data collected with each of the testing devices indicated that there was no significant difference over day, but that a significant difference existed between the three devices.

The differences in scores can be attributed to a number of factors. The primary influencing factors include: 1. differences in the patient installation procedure used in each device, 2. differences in the position of the limb in each device and rotational variance of the tibia, and 3. force application differences in both the soft-tissue compensation procedure and test force application.

Installation procedures can produce variability in results which are specific to each device. The Genucom has a very sophisticated installation procedure which requires careful and accurate digitizing, positioning and clamping of the femur with a specific force. Initial patient positioning is critical as improper seating tends to encourage thigh abduction and external rotation which may affect the repeatability of the measurements. Consistent neutral positioning of the thigh and tibia was maintained with the joint line approximately two inches from the edge of the dynamometer platform. The distal thigh was clamped with medial and lateral forces of approximately 25 lbs and an anterior-posterior compression of 30 lbs. Variation in these forces would result in different soft-tissue compensation values in the six directions of measurement. This variation would affect the test measures to a certain extent. In a similar light, the between-subject variation would be greater in subjects with a large amount of adipose tissue surrounding the knee as this tissue would necessitate large soft-tissue compensation values. It also creates difficulties in identification of the bony landmarks critical to the digitization procedure.

The KT1000 installation was relatively simplistic in comparison to that of the Genucom. The neutral position of both the thigh and tibia was again maintained with precision. The flexion angle was checked throughout the testing to ensure a 30 degree value. Positioning of the patellar sensor pad so that it rested securely on the patella and compressed it into the intercondular groove was an important aspect of the installation.

Erroneous movement in this procedure may have affected the measurement. The tibial sensor component was fairly easy to control for unwanted movement as it could be secured tightly with the velcro strap. The device alignment with the joint line was important to produce an accurate measurement. When the device was attached to the shaft of the tibia, it was at times difficult to maintain adequate alignment in some subjects due to the normal physiologic angulation of the anterior shaft of the tibia relative to the patella.

The Stryker set up procedure, as with the others, involved sitting the subject in a position of neutral femoral and tibial rotation. The joint was positioned at the axis of the distal limb support in order to ensure a consistent flexion angle of 30 degrees (double checked with a goniometer). The tibial attachment was positioned using carefully aligned proximal and distal contacts. The contacts on the tibial tubercle and patellar button were important as the relative displacement measures were recorded from these points.

Variation in limb position was an influential factor in score deviation. Each of the devices carried with it specific limitations to rotational control. In the Genucom, rotation was manually controlled by the operator and values recorded in the test results. This provided for good control through examiner feedback while the test was being performed, but was dependant on neutral initial positioning of the tibia for accuracy. Alternatively, the KT1000 had only a minimal amount of rotational constraint in external rotation, due to the distal foot positioning portion of the apparatus. This lack of rotational control was not necessarily a negative feature as long as the amount of rotation was consistent between tests. However, as the amount of rotation was not measurable, changes in rotation were difficult to discern and may have contributed to the unexplained variance in test measurements. In the Stryker device, rotation of the tibia was constrained to a certain extent by the one inch velcro straps which restrained the ankles around the malleoli. As with the KT1000, the allowable rotation was not measurable, and thus may have contributed to the unexplained variation. In all three of the devices the positioning of the patient was difficult if any type of tibial deformity was present.

The force applied to elicit anterior-posterior displacement in all of the tests may also have caused measurement variation. With the Genucom, the force applied by the examiner could have deviated from its perpendicular application, or the area of force application may have changed, both of which could affect the displacement values. In both the KT1000 and Stryker devices, perpendicular application of the force was influential and under the subjective control of the examiner. Indices of compression or distraction were not available, as in the Genucom results, making the values of A/P displacement more susceptible to unexplained variance. Excess compression normally restricts A/P translation while excess distraction normally facilitates A/P displacement.

The area of force application may have also contributed to variation in the tibial displacement. This occurs if the force was applied over a greater area than normal, thus allowing more force to be transmitted to the tibia which would result in greater displacement values.

Finally, the amount of force applied to the tibia could affect the tibial displacement value. The protocol used in the present study called for recording the tibial displacement at a force application of twenty pounds. This was easily determined in the Genucom from the force-displacement curves. The KT1000 had an internal sensor which indicated a force application of 20 pounds. At this time the displacement value was noted on the dial. The Stryker device required manual force application with a spring-loaded device requiring the operator to carefully control the applied force.

A single examiner was used to perform all of the tests with the devices in order to maintain consistency in examination technique.

5.4.2. RADIOGRAPHIC AND CLINICAL EXAM

In the second section of this investigation, two other test procedures were incorporated along with a population of cruciate deficient knees. The radiographic technique will now be addressed along with the clinical evaluation.

The radiographic evaluation contained some inevitable areas of error production. These areas include: 1. the time lag in force application and picture taking, 2. uncontrolled femoral rotation, and 3. muscular tightness. The time lag between the force application and the taking of the actual radiograph was unavoidable in the positioning of the set up in correct alignment. This may have created errors; the soft tissue onto which the force was applied, tends to dissipate that force with time.

Although considerable care was taken to align the knee such that the radiographic tube was perpendicular to the sagittal plane, it was not always possible to achieve a perfect superimposed shot. The presence of inconsistent femoral rotation in the two radiographs being compared produced possible error in the ability to locate appropriate landmarks. Translation could have been masked by an excess of tibial and/or femoral rotation.

Muscular tightness, as seen in the instrumented devices, may have also prevailed in both the radiographic and clinical exams. Analogous to the KT1000 and Stryker tests, the radiographic procedure positioned the subject in long sitting to enhance hamstring relaxation and provide consistency between techniques.

5.5. CLINICAL AND EXPERIMENTAL APPLICATION OF RESULTS

The clinical application of the results is probably best described by relating it to those test procedures which are fast, accurate and cost-effective. This would include, of course, the clinical manual exam; which although easily applied and cost-effective, has been notoriously unreproducible. The present investigation reflects the clinical examination as being able to indicate cruciate deficient pathology in a given population. This clinical exam must be evaluated with the consideration that all subjects were chosen on the basis of a clinical or arthroscopic examination positive for cruciate deficiency and anterior-posterior laxity. The X-ray technique was also successful in its ability to indicate significant laxity. This technique however is fairly expensive, time consuming and difficult to control for variation in force dispersion secondary to the varying amount of soft tissue. The proportionally greater Genucom scores could have been due to the technical calculation of the displacement curves. As the soft tissue is displaced, a hysteresis occurs due to the differences between the application and release of a loading force. Because of this, there is no way to verify a true neutral position, and the calculated position (taken as the mid-point between the starting positions of the A/P forces) is grater than the true displacement. All three of the devices were able to show significant differences between normal and cruciate deficient knee-laxity measures. In terms of clinical application, all of the test procedures are feasible if the information to be gathered concerns significant asymmetry between anterior-posterior laxity.

In terms of experimental application there were certain differences between the procedures tested. First, the clinical examination is probably the least useful in terms of reproduceability and clinical reporting for experimental analysis. Its subjective nature leads it to a number of unique variations unacceptable to the precision necessary in situations requiring linear displacement values in defined planes. The X-ray procedure is useful although not as convenient and comfortable as the three devices which can be used in an office setting. The Stryker and the KT1000 are both very portable and give a fair degree of clinical information in the documentation of A/P laxity. The experimental value of valid quantifiable documentation is indisputable.

A comparison of the procedures based on the reliability and validity data show that even though all of the procedures were able to identify the cruciate deficient population, they showed much variation in scores. Variation of each procedure indicated that the Genucom was the most variable while the KT1000 the least variable. From highest to lowest variability the procedures could be ranked as follows: Genucom, Stryker, Clinical, X-ray, KT1000. Another important consideration in interpreting the differences in devices is the effect of gravity on the tibial shaft which will cause a relative reduction in the anterior force. This occurs as the force needed to overcome gravity will be subtracted from the twenty pounds of applied force in all techniques except the Genucom which subtracts it out.

In their ability to measure a difference between normal and cruciate deficient knees, the devices can be ranked according to the mean score differences for normal and cruciate deficient knees: 1. Clinical 2.Stryker 3. KT1000 4.Genucom 5. X-ray.

CHAPTER SIX

SUMMARY AND CONCLUSIONS

The investigation of reliability and validity in instrumented knee ligament laxity testing devices is essential prior to their utilization in clinical research. Quantitative measurement of anterior-posterior laxity in the knee joint is a very useful tool in the assessment of clinical pathology pertaining to the cruciate ligaments. It is also an applicable experimental procedure for the assessment of the many operative repair procedures for damaged anterior and posterior cruciate ligaments.

The purpose of this study was to investigate three mechanical devices produced to assess anterior-posterior displacement in the normal and cruciate deficient knee. It was hypothesized that as each of the procedures provided displacement measures in millimeters, the mean score assessed by each measuring device would not show any significant deviation as compared to the x-ray displacement score which was taken as the criterion variable. It was also hypothesized that there would be a significant difference in the measurements of normal versus clinically diagnosed cruciate deficient knees.

6.1. METHODS AND ANALYSIS

In the first part of the investigation, ten subjects were tested on the Stryker, KT1000 and Genucom for two consecutive days. One of these subjects was evaluated ten times on each device while the other nine were evaluated three times and the average taken as their scores. This data was analyzed for Day 1 - Day 2 score differences through 2-factor ANOVA designs with post-hoc comparisons between devices (which were controlled for experimentwise error using Scheffe tests).

The second part of the study was of similar design but included two other evaluation procedures: the clinical evaluation with the Lachman's test at 30 degrees and stress radiographs. Fifteen male subjects with fifteen normal and fifteen cruciate deficient knees were evaluated. The evaluations on each of the devices was done in as close a time frame as possible in order to minimize day to day variation. A two factor ANOVA revealed a difference thus warrenting post-hoc planned comparisons to localize the areas of variability. These comparisons, as with the ones in the first section, were controlled for experimentwise error using Scheffe tests.

6.2. RESULTS AND FINDINGS

The statistical analysis of variables revealed the following in Part I of the study:

1. There was no significant difference between scores collected on two subsequent days with the Genucom, KT1000 and Stryker devices.
2. There was a significant difference between the mean scores collected with the KT1000, Stryker and Genucom -the Genucom scores being significantly different from the KT1000 and Stryker scores in the post-hoc analysis (alpha= 0.05). This was true for the data collected from both a single subject and ten subject series.

In the second part of the study:

1. Each of the five measurement procedures revealed significant differences between normal and cruciate deficient knees.

2. A significant difference was found among the scores of the five measurement procedures (Genucom, KT1000, Stryker, X-Ray, and Clinical) for populations of both normal and cruciate deficient knees.

3. All of the test procedures showed significant mean score differences in orthogonal post-hoc comparisons except for: A) The comparison of the KT1000 with the Stryker in the normal knee population, and B) the comparisons of i) KT1000 and Stryker ii) Clinical and Stryker and iii) Clinical and KT1000 in the cruciate deficient population.

6.3. CONCLUSIONS

The following conclusions may be justified according to the experimental results. They must, however, be viewed in light of the limitations, delimitations and assumptions inherent in the study design.

1. All of the five testing procedures were able to distinguish between normal and cruciate deficient knees.
2. The three instrumented devices, Genucom, KT1000 and Stryker, were all shown to be repeatable in a two day sequential testing.
3. All five test procedures quantified significantly different scores in both normal and cruciate deficient knees - except for the KT1000 and the Stryker.

6.4. IMPLICATIONS

Based on the information in this investigation, there are several implications regarding quantitative assessment of A/P knee ligament laxity. First, it must be emphasized that the clinical Lachman's test (to which all of the procedures were compared) is only a portion of the total clinical assessment on which operative and rehabilitative decision making is based. With this in mind we can look at all of the test procedures in their ability to differentiate between a normal and a pathologically lax knee joint. This laxity in the sagittal plane is most often a result of damage to the anterior and/or the posterior cruciate ligaments which provide the majority of the restraining force in this direction. This ability of the procedures to differentiate may be able to provide supportive documentation to aid in the diagnosis of these injuries as well as record the progress of surgical and rehabilitative processes. In the experimental application, it is critical to be aware of the differences among mean scores in the five testing procedures before comparing laxity measures between devices.

6.5. RECOMMENDATIONS FOR FURTHER STUDY

Based on the findings of the present study, it is the investigator's recommendation that:

1. Further research be carried out in the area of investigation of the variation among measurement procedure scores.
2. The three instrumented devices be used in a wider clinical setting to apply their ability to differentiate knee populations, and test their test-retest reliability over a longer time interval.
3. As the knee joint is essentially a three dimensional

joint in terms of function, and in light of the fact that the ligaments restricting movement at this joint are also three dimensional in structure, a detailed three dimensional analysis of the structural capacity of both normal and damaged joints would be the optimal assessment procedure. As the present study incorporated analysis in one plane, variation within this plane is highly likely to be due to individual restrictions and laxity in the other available planes of movement.

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APPENDICES

APPENDIX I

INFORMED CONSENT FORM

The study that you will participate in is designed to evaluate various testing devices for knee ligament laxity. You will be asked to allow each knee to be assessed by: 1. an experienced orthopaedic surgeon. 2. the Genucom, Stryker and Kt1000 devices (all non invasive devices which are currently in clinical use) and 3. Stress xrays involving two lateral photographs of each knee joint.

You may discontinue your participation in the study at any time simply by asking to do so. That is, you can refuse to complete one or all evaluations or you may ask to have your data results destroyed or withdrawn from comparisons.

It will be possible for you to see the results of your evaluations and to recieve an analysis of your evaluations. AFTER THE STUDY IS COMPLETED, THE DATA COLLECTED FROM YOUR KNEE EVALUATIONS WILL BE RECORDED AND DOCUMENTED WITHOUT INDICATION OF THE SUBJECTS' NAME.

By signing below you are indicating that you consent to participate in the study, that you have read and understand this informed consent form, and that the researchers and the University are not responsible for any injuries which may occur in the course of the experiment.

Signature ______________________

Date ______________________

Address ______________________

Telephone ______________________

APPENDIX II

LAXITY TESTING ASSESSMENT: PATIENT QUESTIONNAIRE

Name______________________________________ Age________________

Address____

Phone____________________

Injury History

Injured Knee________ Date of Initial Injury____________________

Date and Type of Surgery____

Rehabilitation____

Brace____

Subjective Instability: Mild, Moderate, Severe__________________

Incidences of Swelling (per month)______________________________

APPENDIX III

CLINICAL GRADING SCALE

The classification system decribed by Houghston (1976) dealing with rotatory and straight knee ligament instabilities utilized a grading system for the severity of instability. This system was proposed by the Committee on the Medical Aspects of Sports of the American medical Association and was published (1968) in a handbook entitled "Standard Nomenclature of Athletic Injuries".

The grading scale was as follows:

Grade 1+ Mild Instability,
joint surfaces seperate 5mm orless

Grade 2+ Moderate Instability,
joint surfaces separate between 10-15 mm

Grade 3+ Severe Instability,
joint surfaces separate greater then 15mm

For the purposes of this investigation, the scale was modified as follows;

Grade 0 No apparant tibio-femoral displacement

Grade 1 Displacement between 0-5mm

Grade 2 Displacement between 6-10mm

Grade 3 Displacement between 11-15mm

Grade 4 Displacement greater than 15mm

This was a subjective value decided upon by the examining orthopaedic surgeon while performing the Lachman's test.