Research Grant Application for the ACL Study Group:

The Relationship Between Anterior Cruciate Ligament Laxity and Stated Functional Ability

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Location at which the research will be performed:
Hospital for Special Surgery, New York, New York

1. Specific Aims

The specific aim of this study is to determine whether there is a relationship between laxity of the anterior cruciate ligament, as documented by physical examination and by instrumented laxity testing, and stated functional ability of patients.

2. Background and Significance

Patients with anterior cruciate ligament (ACL) insufficiency are often unable to perform activities which require sudden stops and starts, as well as "cutting". Examples of such activities are football, basketball and squash. Some patients with ACL deficient knees are able to participate in these activities to varying degrees.

Orthopaedic surgeons have sought objective and scientific instruments for measuring outcomes in patients. Laxity of the knee in the antero-posterior plane has long been considered to be an important objective criteria in the evaluation of the ACL deficient knee. While this may be true, the direct effect of this variable on patient function remains to be determined.

Measures of ACL laxity have been documented to be both reliable and valid. Previous studies have evaluated strength and function in ACL deficient patients who had been treated operatively and non-operatively. The authors demonstrated that functional testing in a controlled setting is not sensitive enough to detect all individuals who will have difficulties with sports in an uncontrolled environment. However, the degree of laxity was not correlated with function in these investigations. Knee stability may or may not be directly correlated with patient disability or knee dysfunction.

In the recently developed International Knee Documentation Committee (IKDC) knee rating scale, the number of millimeters of laxity is one of the eight criteria evaluated. In this system, the lowest result for a given criteria overrides the other categories and is the patient’s final score. Therefore, using the IKDC knee rating system, increased translation of the knee will lead to a poor evaluation in a patient who may be functioning otherwise well. Although the IKDC has received some criticism for stringent scoring, it reflects the opinions of many leading experts in the field, indicating that laxity of the ACL is an important criteria in the evaluation of these patients. Although the latter statement may be intuitive, it has never been shown to be directly related to patient function.

The relationship between shoulder motion and function has recently been demonstrated in a study that correlated patients’ abilities to perform tasks with their active and passive range of motion. In a recent study, the SF-36 was shown to be correlated to patient outcomes following anterior cruciate ligament reconstruction. However, in this investigation, the authors were not able to demonstrate a significant correlation between the Lachman test or instrumented ligament laxity testing with the patients’ SF-36 scores at baseline. This finding is not surprising in and of itself because
the SF-36 is a generic health status measure and may not possess sufficient sensitivity to detect these specific changes in function. The scale was, however, able to note large changes in patient status after recovery from surgery, particularly with respect to the bodily pain, role physical and physical function subscales.

In summary, there is no evidence that degree of ACL laxity (as measured by physical examination or instrumented testing) is correlated with physical function and ability to perform athletic endeavors.

3. Materials and Methods
3A. Inclusion and Exclusion Criteria

Patients will be identified in the offices of Hospital for Special Surgery (HSS) attending surgeons and in the sports-physiotherapy clinic at HSS. Patients with previous ACL injury who are undergoing non-operative treatment, who are awaiting surgery and who have had ACL reconstruction will be included. Broad inclusion criteria will allow us to examine the effects of knee laxity on function in a wide variety of patients, ensuring generalizability. Sub-group analysis will also be performed to evaluate the potential effect of ACL reconstruction on the relationship between knee laxity and patient function. Patients who have suffered recent injuries (within 3 months) will be excluded because they will not have had a chance to return to sports.

Patients with eighty percent or greater of the strength in the contralateral quadriceps and hamstrings will be also be examined separately as patients with significant weakness may have difficulty with the activities due to the weakness rather than the instability. We will study the effect of weakness on the ability to perform functional tasks.

3B. Data Collection and Analysis

Patients will be examined (Lachman test and Pivot shift test) to determine their degree of ACL laxity. They will also undergo instrumented testing of knee laxity with the KT-1000 arthrometer and quadriceps and hamstring strength testing with the Kin-Kom strength testing machine. Patients will complete the Tegner activity level rating scale and specific questions about their ability to perform activities, their level of symptoms and their ability to jump and pivot. Although the goal of our study is more specifically to study patients’ abilities to perform functional tasks rather than their functional outcome, we will also measure their Lysholm score. We will record co-morbidities relating to the knee (meniscal injury, other ligament injuries, arthrosis), to the contralateral knee, to the rest of the musculoskeletal system and to the patient’s general medical condition. The correlation between the physical examination and the patients’ level of function, ability to participate in sports and ability to “pivot” will be examined.
3C. Sample Size

As per the methodology of Lachin 12, for $\alpha=0.05$ and $\beta=0.20$, with $r=0.70$, 11 patients are required. Stated functional ability will be correlated with two physical examination tests (Lachman and Pivot Shift) as well as the instrumented laxity testing (with the KT-1000 arthrometer) and isokinetic strength testing. Adjustment for multiple correlations indicate that 44 patients are required.

4. Clinical Relevance

The decision whether to operate on patients with ACL insufficiency is often a difficult one for the surgeon 18,20. It can also be a difficult decision to make for the patient. If there is a relationship between ACL laxity and activity level, this information would assist patients and clinicians in determining the best course of treatment for a given individual. We may potentially be able to develop an algorithm for anticipated activity levels in ACL deficient patients treated non-operatively, based on measures of ligament laxity and strength. Patients in whom the decision to undergo ACL reconstruction is difficult would be able to use this information soon after their injury to help decide whether they are willing to accept their "estimated" activity level or whether they would prefer to have surgery. The absence of any correlation between ACL laxity and the ability to perform activities would indicate that other factors are involved and could potentially direct future research initiatives.

Our findings are also potentially generalizable to post operative patients. Knee ligament surgeons are often interested in measuring instrumented laxity in the postoperative period 5,16,22. However, there is no evidence that a more solid reconstruction leads to a patient who is better able to function in high demand activities. In summary, we believe that our study is necessary to achieve an understanding of the relationship between ACL laxity and patient function.

5. References


