Allograft Ligament Reconstruction: Biomechanical Issues and Testing

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Summary: The biomechanical factors that influence the ultimate outcome of ligament reconstruction are described and discussed in the context of experimental studies on allograft reconstruction. Proper choice of animal model and experimental design is emphasized. Selection of appropriate allograft tissue is discussed in terms of the structural properties of the reconstructed bone–soft tissue–bone complex, and the material properties of the soft-tissue substance. The effects of processing and sterilization on graft biomechanical properties are outlined. The requirements for proper initial fixation are presented, and the relative merits of the different methods are discussed. The in vivo changes in allograft properties are shown to be similar to those found for autograft tissues. In general, studies have found that an anterior cruciate ligament allograft with stiffness and ultimate load approaching 30–35% of control values at 1 year postoperatively is typical. Methods used to examine joint kinematics are described, and the results of kinematic analysis of healed allograft reconstructions are summarized. Restoration of normal knee kinematics is emphasized to be the ultimate goal of any ligament reconstruction procedure. Key Words: Ligament—ACL—Allograft—Biomechanics—Kinematics.

The ligaments of the knee are in large part responsible for maintaining normal joint kinematics. Normal kinematics are determined by the geometry of the articulating surfaces, structural and material properties of the ligaments, ligament tension, and the locations of the ligament insertions to bone. Following knee-ligament rupture, alterations occur in the load distribution across the knee joint, which in turn cause abnormal knee kinematics. The purpose of ligament reconstruction is to restore normal joint stability and kinematics, and thus prevent functional instability and subsequent degeneration of the joint. The use of allograft tissues allows this to be accomplished without the morbidity associated with common autograft harvest procedures.

Consideration must be given to several biomechanical factors that affect the ultimate success of ligament reconstruction. Poor graft placement will adversely affect knee kinematics independent of the graft material type, and can result in graft failure from impingement or abrasion. Initial graft tension will influence graft function as a kinematic stabilizer during the early postoperative period, but its relation to graft function after incorporation is unclear. The initial mechanical properties of the graft should not be overlooked. Grafts with insufficient initial strength or stiffness may fail early in the rehabilitation process. Similarly, initial fixation strength must be sufficient to withstand the scheduled rehabilitation and return to activity.

The biological environment, whether intraarticular or extraarticular, can alter the mechanical characteristics of implanted allograft tissues. These changes result from the effects of the graft remodeling process, which includes (a) avascular necrosis, (b) revascularization, (c) cellular proliferation, and (d) remodeling (1). The biomechanical consequences are difficult to predict, but may include

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changes in mechanical properties, fixation strength, and graft tension. All of these factors must be considered when reconstruction procedures are indicated, whether autograft, allograft, or synthetic ligament substitutes are used.

This article identifies important biomechanical issues that must be addressed when considering the use of allograft tissues in knee-ligament surgery. These include the experimental design and animal models used in evaluation of allograft reconstruction procedures, biomechanical considerations when selecting the candidate graft, graft initial mechanical properties, the effects of storage and sterilization techniques on graft properties, graft tensioning and fixation methods, changes in graft tensile properties over time, and kinematic testing of knees to assess the contribution of allograft reconstructions to knee-joint stability and function.

ANIMAL MODELS AND EXPERIMENTAL DESIGN

To biomechanically evaluate new allograft tissues and reconstruction procedures for humans, a surrogate biological model is often necessary. The use of animals in the study of allograft reconstruction is widespread in the literature. Extreme care should be used when reading and interpreting the results of such studies. An investigator selects an animal model and designs the experiment so that the study will be capable of addressing the proposed hypotheses. Consideration must be given to the anatomical closeness to the human condition, the size and ease of use, the amount of data available in the literature, the cost, the immune response of the animal, and ethical issues.

One motivating factor for the choice of an animal model is the information that must be obtained. In the case of anterior cruciate ligament (ACL) reconstruction procedures, attention must be paid to the normal structure and function of the ACL in the animal, to assess where the insertion sites are located, the change in fiber orientation with knee flexion/extension, and differences in the structure of the femur and tibia when compared to that of humans. It should be noted, for instance, that in the stifle of the dog and other animals the knee is normally flexed 30–50° during normal stance (2). Because of such differences, the success or failure of ACL reconstruction procedures evaluated simply by means of restoring normal joint kinematics at time zero will not translate to the human. On the other hand, the healing or immune response of a joint to a prosthesis may be quite accurately modeled (3). A more thorough discussion of the use of animal models in knee-ligament research can be found in (2).

In many cases a simple model that allows the experimenter to address one aspect of the procedure or treatment is most effective. For instance, in (4), the investigators examined the effects of freezing on allograft tissues in an in situ goat model. The ACL and its insertions were submitted to freeze/thaw cycles while the animal was under anesthesia, and then were compared to contralateral control limbs histologically and biomechanically at time zero, 6 weeks, and 26 weeks postoperatively. This experimental design eliminated complications due to variations in bone-tunnel locations and graft tensioning, and thus represents a “best-case.”

In studies of healing in knee ligaments, “sham-operated” controls are sometimes used. This means, for instance, that the contralateral limb receives the same surgical exposure—a sham operation—as the limb in which the ACL was reconstructed. Similar designs are used in the study of drug delivery systems in vivo. This approach provides at least one advantage: Because each limb received the same surgical treatment, the effect of the surgery can be eliminated in comparisons between limbs. If one desires to know the effect of the surgical procedure, an additional group can be used as an external control group (5).

In all experimental studies, a good experimental design relies on proper choice of statistical procedures and the levels of statistical significance and power. A cautious reviewer of the literature will pay close attention to these points when interpreting biomechanical studies. Although these topics are beyond the scope of this article, a discussion can be found in an article by Bulter (6).

ALLOGRAFT SELECTION—BIOMECHANICAL CONSIDERATIONS

Selection of appropriate allograft tissues has been based on issues such as the ultimate load of the candidate tissue, sterilization and availability, immunogenicity, and potential for vascular ingrowth. Certainly, initial tensile properties are important for graft selection; however, the ultimate load of the tissue is not the only important parameter. Graft stiffness and material characteristics also merit serious consideration.
To appreciate the biomechanical factors that are important to proper graft selection, the tensile properties of the graft must be understood. When testing a bone–soft tissue–bone complex, one usually is interested in determining both the structural properties of the complex (as determined from the load–elongation curve) and the material properties of the soft-tissue substance (as determined from the stress–strain curve) (Fig. 1). Structural properties that are commonly reported for tensile test data include the ultimate load, ultimate elongation, stiffness, and energy absorbed to failure. These structural properties are affected by the tissue material properties, the geometry of the tissue (i.e., cross-sectional area) and the strength/stiffness characteristics of its insertions to bone. Material properties include the tensile strength, ultimate strain, and tangent modulus. Stress is determined by dividing the applied load by the tissue initial cross-sectional area. Several methods have been employed to obtain area measurements on soft tissues (8,9). Material properties describe the material characteristics of the soft-tissue substance itself, affected in part by the organization, orientation, and type of collagen fibers, as well as interactions with other matrix constituents. The stiffness and tangent modulus refer to the slope of the load–elongation and stress–strain curves in the linear portion, respectively. Energy absorbed to failure is defined as the area under the load–elongation curve.

The experimental determination of the tensile properties of soft tissue grafts poses several unique problems. The simplest approach would be to test the isolated tissue; however, clamping the ends of the tissue has proven difficult. The length-to-width ratio of most ligaments is too small to achieve a uniform stress distribution during tensile testing. To remedy these problems a bone–ligament–bone complex is used. This preparation provides secure clamping and better approximates in situ conditions, but the test results from such specimens are a result of contributions from both the hard- and soft-tissue properties, making it difficult to isolate the properties of the ligament substance from those of the insertions to bone. Measurement of strain in the central portion of the soft tissue is necessary to obtain material properties representative of the tissue itself (10).

In some testing situations, simultaneous measurement of structural and material properties is not possible. Determination of material properties of the ACL is made especially difficult because of its geometry. Multiple bands of twisting fibers make it impossible to obtain a uniformly stressed tissue for material parameter estimation in its intact state. To alleviate this problem, several investigators have chosen to test individual bundles (or functional bands) to determine material properties (11,12). In this case, the structural properties of the femur–ACL bundle–tibia complex have little or no meaning.

An illustration of the importance of graft structural properties can be seen in the following example (Fig. 2). One can envision many different grafts that would have ultimate loads similar to that of the human femur–ACL–tibia complex (FATC), but with large differences in ultimate elongation, stiffness, and energy absorbed. Graft A matches the ultimate elongation of the human FATC, but presents different values for the ultimate load, stiffness, and energy absorbed. Graft B has the same ultimate load as the human ACL, but its stiffness is

**FIG. 1.** Idealized load–elongation and stress–strain curves for a bone–ligament–bone preparation under uniaxial tension. A: Structural properties; B: Material properties. Adapted from (7).
lower, and the energy absorbed and ultimate elongation are greater. Thus graft A would be in general too stiff, whereas graft B would be too compliant. The ultimate load normally used as a ‘gold standard’ for human FATC is 1,725 ± 269 N (14), whereas the stiffness has been reported as 182 ± 33 N/mm (15). Ultimate load and stiffness values for the patellar tendon graft have been reported as 2,734 ± 298 N and 650.6 ± 85.4 N/mm, respectively, both far higher than that of the native FATC. However, when one considers the changes in graft properties that occur following implantation in vivo, it is evident that information other than just initial graft tensile properties is needed. The degradation of graft properties in vivo for different allograft tissues must be known in order to choose a graft that has the optimal chance for long-term success.

It should be noted that the structural properties obtained for the human FATC are sensitive to factors such as specimen orientation (16), knee-flexion angle (17), loading rate, and donor age (14,16,18). Similar observations have been reported for other graft tissues as well. These effects can cause large discrepancies in mechanical data between studies, and thus add confusion to the graft selection process. A uniform test procedure should address these issues, and allow for ease of testing and comparison with other relevant studies.

Often the mechanism of failure of the complex can yield important insights. If a bone-soft tissue-bone complex fails at the insertion to bone, the tensile strength and ultimate strain were not obtained; however, this indicates that the insertion site was the weakest link in the complex. Analysis of the failure modes of complexes with different fixation methods in reconstructed knees can help to identify methods that provide insufficient fixation strength in comparison to the ultimate load of the graft tissue.

DATA ON CANDIDATE GRAFT INITIAL PROPERTIES

One factor governing the success of an allograft reconstruction is its initial mechanical properties. By comparing candidate graft tissues with one another, and with the normal ACL mechanical properties, one can determine which tissue will be most appropriate in terms of initial strength, stiffness, and energy absorbed. In some cases, sufficient initial strength and stiffness can be provided by “doubling over” a graft tissue to increase effective cross-sectional area. To estimate the increase in structural properties by such a procedure, data on the graft material properties must usually be known.

The initial material properties of candidate allograft tissues vary widely (Table 1). It is generally agreed that allograft tissue should have stiffness and ultimate load characteristics greater than those of the native ACL, to accommodate early decreases in these values from tissue necrosis and remodeling. When using larger amounts of tissue with ultimate stress and modulus values below those needed, it may be necessary to use larger drill holes to accommodate the increased mass of tissue at the ends. This may slow bone ingrowth and thus, graft incorporation. Use of grafts with stiffness and ultimate load values below those of the initial structure may require longer periods of protection and controlled rehabilitation to prevent premature failure.

In general, the data presented in Table 1 are for young donors. It is widely recognized that the strength/stiffness characteristics of the ACL are a function of donor age, tending to decrease with increasing age (14). One would think it reasonable to assume that other graft tissues characterized by insertions to bone at both ends could undergo similar decreases in mechanical properties with donor age. Thus a particular graft tissue could possess initial mechanical properties quite different from those reported. However, animal studies have shown that, in contrast to data available for the human ACL, the structural and material properties of canine patellar tendon were not affected by increased donor

\[ \text{LOAD} \]
\[ \text{DEFORMATION} \]

\[ \text{GRAFT A} \]
\[ \text{HUMAN FATC} \]
\[ \text{GRAFT B} \]
**TABLE 1. Initial mechanical properties of common allograft tissues used in knee-ligament reconstruction**

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Ultimate load (N)</th>
<th>Stiffness (N/mm)</th>
<th>Energy absorbed (Nm)</th>
<th>Ultimate stress (MPa)</th>
<th>Ultimate strain (%)</th>
<th>Modulus (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACL</td>
<td>1.725 ± 269</td>
<td>182.0 ± 33.0</td>
<td>12.8 ± 22</td>
<td>35.0 ± 5.0a</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>PT (central third)</td>
<td>2.900 ± 260</td>
<td>685.2 ± 85.6</td>
<td>12.8 ± 2.4</td>
<td>68.3 ± 2.1b</td>
<td>12.0 ± 2.6a</td>
<td>N/A</td>
</tr>
<tr>
<td>PT (medial third)</td>
<td>2.734 ± 298</td>
<td>650.6 ± 85.4</td>
<td>12.8 ± 2.2</td>
<td>68.3 ± 2.1b</td>
<td>12.0 ± 2.6a</td>
<td>N/A</td>
</tr>
<tr>
<td>Fascia lata</td>
<td>628 ± 35</td>
<td>118.0 ± 5.0</td>
<td>3.0 ± 0.4</td>
<td>78.7 ± 4.6</td>
<td>7.7 ± 2.3b</td>
<td>N/A</td>
</tr>
<tr>
<td>Semitendinosus</td>
<td>1.216 ± 50</td>
<td>186.1 ± 9.2</td>
<td>8.9 ± 0.5</td>
<td>88.5 ± 5.0</td>
<td>8.2 ± 2.5b</td>
<td>N/A</td>
</tr>
<tr>
<td>Gracilis</td>
<td>838 ± 30</td>
<td>170.9 ± 11.0</td>
<td>3.5 ± 0.4</td>
<td>111.5 ± 4.0</td>
<td>7.0 ± 1.9c</td>
<td>N/A</td>
</tr>
</tbody>
</table>

ACL, anterior cruciate ligament; PT, patellar tendon; N/A, data determined from tissue strain measurements were not available.

a Mean ± standard deviation. Except where indicated, all values from (15).
b From (11).
c From (19).

age (20), and that these data agree with preliminary data for the human patellar tendon as well (21). The reason for the differential aging effects in human graft tissues is unknown, but may be related to tissue physiological function, mechanical environment, blood supply, or differences in the repair response to accumulated damage.

**EFFECTS OF PROCESSING AND STERILIZATION ON GRAFT BIOMECHANICAL PROPERTIES**

When allograft ligament reconstructions were first performed, tissues were harvested under "sterile" conditions, and then preserved fresh-frozen until they were needed. Presently, tissues are commonly collected under sterile conditions with careful screening of donors, or under "clean" conditions, processed by freezing or freeze-drying, and then possibly submitted to some type of sterilization procedure. Although careful donor screening is used for tissues procured for allograft transplantation, the effectiveness of this screening is not complete. For instance, there is a period during which donors will test negative for the human immunodeficiency virus (HIV) despite being infected. To reduce cost and increase supply while avoiding the transmission of infectious diseases, freeze-dried preservation as well as gas sterilization and cobalt irradiation methods have become common. Although these are the most widespread, other techniques including boiling, autoclaving, antibiotic soaking, and chemical sterilization have been used to prepare allogeneous tissue for implantation. Freeze-drying and deep-freezing have been thought to reduce the antigenicity of donor tissues, whereas gas sterilization and cobalt irradiation reduce the risk of infectious disease transmission. These methods of preservation have recently been shown to affect the mechanical properties of graft tissues (22-25), and thus preservation has become an important issue in graft selection.

An acute synovial reaction to sterilization has also been reported (26). A characteristic intraarticular reaction was observed in 6.4% of a series of patients receiving a bone-patellar tendon-bone allograft sterilized with ethylene oxide. These patients underwent arthroscopic graft removal. Results of the analysis of removed synovial fluid, tissue, and allograft by gas chromatography demonstrated detectable levels of ethylene chlorohydrin, a reaction product of ethylene oxide sterilization that has been shown to cause toxic reactions in biological tissue. Particulate debris was present within the joint in all patients. In several patients, the bony tunnels used for allograft reconstruction of the ACL were filled with fibrous tissue, and the grafts showed no evidence of incorporation. There was a severe cellular reaction present within the synovial tissue as well. Paulos and colleagues (27) also reported similar foreign-body-type reactions to ethylene oxide-sterilized patellar tendon allografts, both in the intraarticular area and at the attachment sites. A ganglion-like cyst formed in some cases at the tibial attachment site. These findings demonstrate that although the effects of sterilization on the initial graft properties are very important, the ultimate incorporation of the graft can be affected by sterilization residue products, and these effects may be significant.

Jackson and associates (4) designed an experimental procedure to freeze the ACL in situ, and to investigate the effects of devitalization and biological incorporation on a collagen graft. The model simulated a biological autogenous graft in which the collagen fibers are anatomically oriented and fixed under physiological tension. Goats were evaluated at time zero, 6 weeks and 26 weeks postoperatively.
Results demonstrated that there was a significant increase in cross-sectional area at both 6 weeks and 26 weeks, and the difference between experimental and control ACLs increased with time. At 6 weeks, there was a significant reduction in the ultimate load, but this difference was not present at 6 months. Because the cross-sectional area was increased at 6 months, but the ultimate load was not different from that of control, this implies that the tensile strength of the tissue had decreased. Morphometric analysis demonstrated an increase in the production of small-diameter collagen fibrils, and speculation was made that the increased cross-sectional area could also be due to appositional formation of new collagen on the surface of the "dead" ACL. The authors concluded that despite the freezing, the ACL retained its former structural properties during revascularization and repopulation. Other studies have also demonstrated that deep-freezing or freeze-drying of ligament tissues after procurement produces little or no change in mechanical properties (24,28,29).

$^{60}$Cobalt $\gamma$-irradiation has also been popular for secondary sterilization. This methodology has proven to be both safe and effective (30) without the toxic byproducts associated with ethylene oxide sterilization. It also has been shown that if the exposure level is kept below 3 Mrad, there is no effect of radiation on the strength of bone in compression, torsion, and bending (31). In the case of patellar tendon–bone units, differing results have been reported. Haut (32) reported that 2 Mrad of radiation had no effect on the material properties, whereas a subsequent study (33) showed a significant effect. Paulos and colleagues (27) and France and co-workers (34) reported a 50% reduction in tensile strength for patellar tendon–bone units when compared to fresh–frozen and freeze-dried specimens, at a radiation level between 2.5 and 3.5 Mrads. More recent work by Haut and Powlison (23) showed that a difference between 2 Mrad-irradiated patellar tendon–bone units and frozen ones could be demonstrated when the tendons were tested in a saline bath at 37°C, but no difference was found when they were tested in air. This emphasizes the importance of test environment in evaluating graft mechanical properties. A more recent study by Gibbons and associates (22) showed that although 2 Mrads had no effect on patellar tendon properties, 3 Mrads caused a significant decrease in all measured structural and material properties when compared to controls. The general conclusions were that $^{60}$Co $\gamma$-irradiation produces dose-dependent reductions in graft mechanical properties, affecting all parts of the tendon–bone complex, and that failure properties were affected more than the subfailure properties.

It is clear that $\gamma$-irradiation provides the safest option for sterilization of grafts harvested under clean conditions. It has been documented that 2.0 Mrad of radiation inactivates many bacteria and viruses (35). This method of sterilization eliminates problems caused by any toxic byproducts, and provides tissue banks with access to many tissues that would otherwise be screened out. Nevertheless, careful screening is necessary, and sterile procurement is still popular. If the long-term in vivo results of irradiated graft tissues are positive, clean procurement with secondary sterilization will likely become the method of choice for graft harvest. In either case, it must be cautioned that the mechanical properties of sterilized grafts change drastically after implantation, and may follow a different course of recovery than nonsterilized tissues.

**FIXATION METHODS**

Despite the best surgical technique, the initial weak link in a reconstruction will usually be its attachment to bone. Until the ends become incorporated into bone, the graft will be vulnerable to failure. Rehabilitation (which includes forces and movements related to a return to full range of motion) should be selected carefully during early postoperative periods to avoid loosening or failure of graft attachments.

Essentially two broad categories of allograft tissues are used—those implanted with bone blocks, and those consisting of only soft tissue. Each graft requires a different type of fixation, the former generally needing interference fixation in a bone tunnel or trough, and the latter requiring cortical-bone fixation. Allografts implanted with bone blocks rely on bony ingrowth into the blocks and associated soft tissue in the bone tunnel for final fixation, whereas grafts consisting of collagenous soft tissue generally require that the ends become incorporated into newly formed bone in bone tunnels. The effectiveness, extent, and timing of bone ingrowth occurring with these methods has not been documented experimentally. Tissues without bone plugs are usually passed through bone tunnels and then attached to cortical bone. This is usually accomplished with
staples, sutures with bone screws, or spiked washers. In the case of spiked washers or plates, either the ends of the tissue are placed directly beneath the fixation device, or a suture is attached to the tissue and then wrapped around the washer. Grafts with bone plugs at the ends are usually secured in the bone tunnels with interference screw fixation, or by passing a suture through the bone block and tying this off to a screw in the cortical-bone exterior to the tunnel.

Three clinical goals have been identified as important when considering fixation of graft ends (36): (a) the fixation must be rigid enough to maintain joint stability under repetitive loading; (b) the fixation must resist sudden traumatic loads; and (c) the biologic graft must become incorporated, so that the force on the structure is no longer resisted by the fixation device. The first goal requires the graft to possess adequate fatigue resistance. The second requirement is important during the initial postoperative period when bone incorporation of the graft has not yet occurred. The third requirement prevents the graft from remaining at risk for injury after retrieval, failure, or resorption of the fixation device.

Mechanical testing can provide an idea of how well a fixation method addresses these points. Failure testing is designed to assess the response of the fixation method to a sudden overload event, and cyclic testing provides an indication of how repetitive loading will affect the fixation. The cyclic tests are usually performed at low speeds to simulate rehabilitation or walking, whereas the failure tests are performed at high speeds to simulate traumatic injury. Cyclic tests can be performed by repetitively applying a given load to the graft and monitoring the increase in elongation (cyclic creep), or by repetitively stretching the tissue to a given elongation and monitoring the decrease in load (cyclic stress relaxation).

Only one study has examined the response of graft fixation to cyclic loading. Burks and co-workers (37) measured the response of three fixation procedures and three tissue types used for ACL reconstruction to continuous passive motion (CPM). The three clinical reconstruction procedures were (a) prepatellar retinaculum and quadriceps and patellar tendon run "over the top" and secured with staples and screws, (b) the central one-third patellar tendon–bone graft placed in 9-mm tunnels and secured with 6.5-mm cancellous bone screws, or (c) a semitendinosus tendon looped over a bony bridge proximally and secured at both ends with AO washers and screws. Then CPM was performed between 20 and 70° of knee flexion, and anterior–posterior (AP) knee laxity was measured before and after testing. All of the patellar tendon grafts failed during the CPM at the tibial attachment, as the bone block pulled past the interference screw. Of the semitendinosus grafts, 60% failed at the femoral end. The best performers were the retinacular tissues, which had no gross failures following testing. It appears that the failure at the fixation sites of many of these grafts might have been due to poor bone stock, as the tissues were from older donors.

Several other studies have measured the initial fixation strength of different fixation methods (38–40). Robertson and co-workers (39) examined the strength of fixation by spiked soft-tissue washers and plates, barbed staples, stone staples, and sutures. Capsular, tendinous, and extensor mechanism tissues were used in the analysis. For all three tissues, the ultimate load of the fixation was superior for the spiked washer and soft-tissue plate methods. Kurosaka and colleagues (38) tested three fixation techniques with patellar tendon grafts to determine the structural properties associated with them. The methods were (a) tying sutures over buttons, (b) staple fixation, and (c) interference screw fixation. The interference fixation had a significantly higher stiffness than the other two methods, but otherwise no statistical differences were measured. In the second part of the study, the effect of interference screw diameter was assessed using patellar tendon grafts. Both 6.5-mm and 9.5-mm diameter interference screws were used to fix the graft in a 9.5-mm diameter drill hole. The larger diameter screw produced significant increases in the stiffness and ultimate load, with close to 100% increases in both variables. Daniel (41) pointed out that one of the most important parameters for interference screw fixation is the gap between the bone block and the drill hole wall; thus, drill hole size and interference screw diameter should be chosen based on the size of the graft bone blocks.

Other methods of fixation used clinically include (a) round fixation "buttons" placed over the end of a bone tunnel and then attached with suture to a graft tissue, (b) devices that are attached to the graft and then into the bone tunnel from the intraarticular side to achieve an interference fit, and (c) oblong buttons that can be passed through the bone tunnel and then flipped up to prevent passage back through
the tunnels. The last two "endoscopic methods" do not require an incision on the extraarticular side. The effect of adding a suture between graft tissue and the fixation device should be considered when using these methods—the compliance of the suture and the slippage that can occur at its attachment points can greatly alter the stiffness characteristics of the graft complex. In all cases, the shortest length of suture that can accomplish the task is optimal.

CHANGES IN GRAFT PROPERTIES IN VIVO

To determine an appropriate allograft substitute for ligament reconstruction, one must account for the inevitable degradation of both structural and material properties that have been documented to occur in vivo (42–47). Much of the research has been performed using a canine model (Table 2). The results of the summarized studies are highly divergent, mainly because of differing experimental designs and protocols, animal models, graft types, procurement and sterilization techniques, and surgical procedures. For instance, in a 1987 study (49), the grafts in three out of eight dogs survived the 9 months of the study, whereas all other grafts were failures. It is impossible to say whether the three grafts that survived the study are representative of the healing response of the group, and the failure of the other five grafts is most likely a sign of a significant problem with the reconstruction procedure.

In a study examining the reconstruction of the canine ACL with allograft patellar tendon, Shino and associates (50) found that allografts sustained 35% of control ultimate load values at both 30 and 52 weeks postoperatively, whereas the mean energy absorbed was 41% and 57%, respectively. These values were very similar to those obtained for autografts implanted under the same conditions. Failure modes included both the tissue substance and the tibial attachment site. Drez and co-workers (43) reported stiffness (ultimate load) values of 30(43)% and 27(43)% of control at 6 and 12 months postoperatively. In this study, failure modes included the tissue substance as well as both the femoral and tibial graft attachment sites. Jackson and associates (46) reported on the results of replacement of the ACL with an allograft ACL in a goat model. Animals were sacrificed at 1 year postoperatively. At this time reconstructed knees had significantly increased primary and secondary laxity, with the total AP laxity more than three times that of the controls. The FATC stiffness (ultimate load) was 35(25%) that of the controls. The reconstructions had oriented collagen fibers, a well-developed vascular network, and a lack of cellular (immune) infiltration. A subsequent study examining the addition of a ligament augmentation device (LAD) found that total AP laxity was slightly decreased and that ultimate load and stiffness were much higher than those without augmentation, but were still significantly different from control values.

In summary, these studies have shown that an ACL allograft with stiffness and ultimate load approaching 30–35% of control values at 1 year postoperatively is typical. These results are slightly less than those summarized for ACL autografts elsewhere (48). Stress shielding of the allograft from high loads by use of a LAD in the early healing stages may produce a stronger reconstruction in the long run (45). The medial collateral ligament (MCL) allografts appeared to be much more successful than ACL allografts, but were inferior to autografts and underwent a gradual decrease in strength and stiffness over time (44,51). As with autografts, tissue remodeling after implantation results in drastic changes in graft properties during the early postoperative period, with gradual revascularization, cellular repopulation and proliferation, and development or production of well-aligned collagen fibers.

**TABLE 2. Stiffness/ultimate load of allograft tissues as a function of postoperative healing time**

<table>
<thead>
<tr>
<th>Allograft (ref.)</th>
<th>Structure replaced</th>
<th>Animal</th>
<th>Postoperative healing time (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexor tendon</td>
<td>ACL</td>
<td>Canine</td>
<td>6–8</td>
</tr>
<tr>
<td>Fossa lata</td>
<td>ACL</td>
<td>Canine</td>
<td>15–17</td>
</tr>
<tr>
<td>Patellar tendon</td>
<td>ACL</td>
<td>Canine</td>
<td>15–17</td>
</tr>
<tr>
<td>ACL (49)</td>
<td>ACL</td>
<td>Canine</td>
<td>15–17</td>
</tr>
<tr>
<td>ACL (64)</td>
<td>ACL</td>
<td>Canine</td>
<td>15–17</td>
</tr>
<tr>
<td>Patellar tendon</td>
<td>ACL</td>
<td>Canine</td>
<td>15–17</td>
</tr>
<tr>
<td>Patellar tendon</td>
<td>MCL</td>
<td>Rabbit</td>
<td>15–17</td>
</tr>
<tr>
<td>ACL (45)</td>
<td>ACL</td>
<td>Goat</td>
<td>15–17</td>
</tr>
<tr>
<td>ACL w/ LAD (46)</td>
<td>ACL</td>
<td>Goat</td>
<td>15–17</td>
</tr>
</tbody>
</table>

ACL, anterior cruciate ligament; MCL, medial collateral ligament; LAD, ligament augmentation device.

* Experimental/control × 100 (48).


**KINEMATIC TESTING**

The restoration of normal knee kinematics is the ideal goal of a ligament reconstruction procedure. In the clinical setting, common measures of knee kinematics include subjective scoring methods such as the anterior drawer, Lachman, and pivot shift
tests. These methods provide a convenient way to assess preoperative deficiency and postoperative progress, but the values obtained can vary between examiners. The results of these tests are also affected by muscle tone, and thus right-to-left comparisons by the same examiner are essential to obtain meaningful results. In an effort to reduce some of the variability associated with these methods, commercially available knee analysis systems have become popular. These have helped to reduce the variability associated with the subjective scoring methods, but other problems have become evident (52,53). All these methods attempt to make some measure of the kinematics of the knee joint. Here a brief introduction to the kinematics of rigid bodies will be presented, followed by a discussion of commonly used measurement methods. Finally, the experimental results of kinematic measurements on allograft-reconstructed knees are presented, and the effects of initial tension and drill hole location on AP laxity measurements in reconstructed knees are discussed.

The knee can be thought of as a system of two (or three, with the patella) rigid bodies attached by soft tissues. This description is reasonable because the deformations of the soft tissues and the motions of the femur relative to the tibia are much larger than the deformation of the bones. The knee is a 6-df system, and thus three translations along three axes and three rotations about these axes are needed to fully describe the relative position of the femur and tibia. A 6-df joint represents the most general mechanical model of any joint. The motion of some joints can be represented by a simpler mechanical model (i.e., the hip behaves as a ball joint), but the generality of the description that follows allows its application to the description of the motion of any joint.

In experimental studies of knee joint kinematics, "embedded" coordinate systems are constructed in the femur and tibia, aligned so that clinically relevant measurements of motion can be obtained (Fig. 3). Here, for instance, the y-axes are aligned along the long axes of the bones, the z-axes are oriented anteriorly, and the x-axes are directed medially. Usually, a consistent method of establishing these axes is based on anatomical landmarks. An example of a standard for defining these coordinate systems is described by Grood and Suntay (54). The relation between the femoral and tibial coordinate systems at any given time completely describes the spatial relationship between the bones. Although this procedure may not be explicitly performed for clinical laxity measurements, the inherent assumptions are equivalent.

Let $X_f, Y_f,$ and $Z_f$ be the unit vectors defining the femoral coordinate system, and $X_t, Y_t,$ and $Z_t$ be unit vectors defining the tibial coordinate system. If the vector $v_i$ represents the coordinates of a point on the tibia with respect to the tibial coordinate system, the vector describing the same point in the femoral coordinate system $v_f$ is given by:

$$[v_f] = [R] \cdot [v_i] + [t]$$

Here $R$ is an orthogonal $3 \times 3$ rotation matrix, and $t$ is the vector that locates the tibial coordinate system origin $O_t$, with respect to the femoral coordinate system origin $O_f$:

$$[R] = \begin{bmatrix}
R_{11} & R_{12} & R_{13} \\
R_{21} & R_{22} & R_{23} \\
R_{31} & R_{32} & R_{33}
\end{bmatrix}, \quad [t] = \begin{bmatrix} t_x \\ t_y \\ t_z \end{bmatrix}$$

The total transformation between the coordinate systems can be thought of as a rotation about a line in space followed by a translation. To determine the nine components of the rotation matrix $R$ and the three components of the translation vector $t$ at any time, one must at least know the coordinates of three noncolinear points on the femur, and three noncolinear points on the tibia in a global coordinate system, and the coordinates of these points with respect to the embedded coordinate systems. Once $R$ and $t$ are known, all clinically relevant motion parameters, such as AP tibial translation, tibial
rotation, or varus–valgus rotation, can be derived from their components. In the case of a joint that has \( < 6 \) df, some of the components of \( R \) and \( t \) may be known without measurement. For instance, in the case of a ball joint like the hip, all three translation components of \( t \) should be zero. If the elbow is treated as a hinge joint, then not only will the components of \( t \) be zero, but also the components of \( R \) are specified such that rotation about only one axis is allowed.

Many different experimental methodologies have been designed to allow the determination of the matrices \( R \) and \( t \). Two of the most common methods are electromechanical linkages and stereophotogrammetric methods (determination of 3-D coordinates of points from two 2-D views). The latter method is the principle on which 3-D gait analysis is based. These methods have proved extremely useful in an experimental setting; however, both have drawbacks for clinical use. These drawbacks are related to the inability to accurately determine the motions of the bones because of the overlying soft-tissue structures. Because of this, methods that subjectively measure motion under constrained conditions such as the anterior drawer, Lachman, and pivot–shift tests are used clinically. Stress radiographs are also commonly used. These methods usually look at the motion in one direction (i.e., the displacement of a point on the tibia relative to another on the femur). They may or may not constrain motions in other directions during the testing. For instance, during an anterior-drawer test, the tibia is displaced anteriorly with respect to the tibia; however, the tibia may simultaneously rotate around its axis. In this example of "coupled" motion, restricting the rotation of the tibia will decrease the measured anterior displacement for a given applied load. Further, the "neutral position" from which the test is begun is somewhat arbitrary, and thus total AP displacement provides a more objective measure. The clinical tests allow the quick assessment of ligamentous insufficiency in a clinical setting, and are useful to assess the progress of a patient. Because the normal knee laxities of individuals and the manner in which the tests are performed (magnitude of load applied, which df are unrestricted) vary greatly, comparisons between patients or between examiners can sometimes be meaningless.

The idea that the joint can be positioned to most effectively assess the status of one of its ligamentous structures has been used to construct externally mounted measurement devices, commonly referred to as arthrometers or knee laxity testing systems. Two of the most popular systems are the Genucom knee analysis system and the MED metric KT-1000 arthrometer. The repeatability of these measurement devices between trials and installations has proven to be good (52,53), but it has been recommended that paired differences should be used rather than individual knee measurements. Care must be taken in interpreting the results of a single measurement, because they have been shown to vary significantly from day to day. The measurements obtained from these devices are also strongly dependent on the site at which load is applied.

When testing knee-joint laxity under constrained conditions, a nonlinear curve is the result of force–displacement or torque–rotation measurements. For instance, in testing the AP laxity of knees, the force–displacement curve has an initial low-slope region (referred to as the initial stiffness or primary laxity region), and then at higher applied loads exhibits a second high-slope region (terminal stiffness or secondary laxity region). This response is the result of the gradual recruitment of knee-joint structures to resist the applied loads. Many experimental investigations will report stiffness or displacement values for both regions. In general, it is important to remember that these measurements are highly dependent on the df allowed, the method of determining the joint neutral position, flexion angle, knee-joint compressive load, and the presence or absence of muscle forces.

The results obtained in experimental studies have, in general, shown a decrease in stiffness and/or increase in laxity for allograft-reconstructed ACLs in comparison to preoperative or contralateral control values. Holden and co-workers (55) examined the results of fascia lata reconstruction of the ACL at time 0, 2, 4, and 8 weeks postoperatively in a goat model. A custom fixture was designed to accomplish AP testing at 45° of knee flexion because preliminary studies demonstrated that the greatest increases in AP laxity following ACL sectioning occurred at this angle. Proximal–distal translation of the tibia was allowed during testing, but tibial rotation was constrained. Regions of primary and secondary translation as well as the stiffness at 30 N applied load were defined on the force–displacement curve. Knees with fascia lata autografts had lower anterior stiffness values than the controls, with no group >40% of the control values. All experimental knees had greater total AP tran-
lation than did controls. Most of the change was due to increases in primary laxity, with small increases in secondary laxity. Jackson and associates (46) reconstructed the goat ACL with freeze-dried ACL allografts, and examined the results at 1 year postoperatively. The total laxity of reconstructed knees was 3.8 times that of the control knees, and differences in the primary laxity were responsible for 80% of the difference in the total laxity. The AP stiffness at 30 N applied anterior load was only 50% of the control values. A subsequent study (45) examined the same reconstruction with an allograft ACL and LAD that was released at 3 months postoperatively. Again, the total AP translation of reconstructed knees was significantly greater than that of control knees (3.1 times that of control values), and 59% of this difference was due to increases in primary AP translation. The AP stiffness at 30 N applied anterior load was only 35% of control values.

Recently, Drez and colleagues (43) reported on the results of ACL reconstruction with allograft patellar tendon at 6 and 12 months postoperatively. Measurement techniques for laxity testing were identical to those used in the two previously described studies. No significant differences in any of the quantities derived from the AP measurements could be found between the 6- and 12-month groups, and, thus, results were averaged. The total AP laxity of reconstructed knees was 4.3 times that of control knees, and again was in great part due to increases in primary AP translation (15-fold increase compared to controls). Anterior stiffness of experimental knees was 39% of control values. Many other experimental studies have reported data for kinematic testing of allograft-reconstructed knee ligaments, but the previous studies are unique in that the same animal model and experimental methods were used for each study, facilitating comparisons between studies. Increases in primary laxity are most likely due to the concurrent findings that the structural properties had decreased drastically in comparison to control values. Other structures have a greater contribution to resisting motion in the region of secondary laxity. It may also be due to a decrease in graft tension during the postoperative healing period.

Subjective methods of assessing knee laxity in clinical studies have in general reported much more success than experimental studies for allograft ACL reconstruction. Although a review of all the relevant clinical literature is beyond the scope of this article, studies have shown that a large percentage of patients in retrospective analyses felt that their knees were "normal" in relation to stability and the feeling of "giving way." Examination by methods such as the Lachman anterior–drawer, and pivot–shift tests also indicates excellent results. It is not entirely clear why the clinical results of allograft ACL reconstruction have proven superior to experimental results, although the errors inherent in clinical measures of joint kinematics may play a role. Other factors include differences in the anatomy and healing response of the animal models in comparison with the human, adherence to rehabilitation regimens, postoperative care, and differences between the in situ experimental measurements and the in vivo measurements made in the clinical setting.

The initial attachment location and graft tension of the allograft can greatly affect the contribution of the allograft to joint kinematics. One approach to assessing proper graft positioning for the ACL and posterior cruciate ligament (PCL) has been to determine regions of the normal insertion site locations that result in the least length change through a range of motion (56–58). This is based on the idea that locations providing graft "isometry," or the lack of length change in the graft through a range of motion, will in some sense be the optimal location for the bone tunnels. However, this does not directly ensure that proper knee kinematics will be restored. Studies have demonstrated that the femoral insertion site location had a much more significant effect on the isometry than did the tibial insertion site in the case of the ACL (57,58).

A subsequent study by Bylski-Austrow and coworkers (59) demonstrated that there is an interaction between the effects of attachment location, flexion angle at initial tensioning, and the initial tension on knee-joint kinematics. In this study, intact knees were subjected to a range of knee flexion while under a 100-N anterior tibial force. Then, the distance of a point in the tibial insertion and selected points in the femoral insertion of the ACL was measured under the same loading circumstances. Finally, the ACL was sectioned and then reconstructed using a flexible cable. For each of the femoral attachment sites, initial tensions of 22 and 44 N were used, at flexion angles of 0 and 30°. Knee flexion angle and AP translation were determined from kinematic data obtained using an instrumented spatial linkage. It was found that the distances between the femoral and tibial attachment locations
increased with increasing flexion for femoral attachment anterior to the natural insertion, decreased for posterior sites, and decreased to a lesser extent for distal sites. The forces measured at 90° flexion were larger when the initial tensioning was performed at 30° flexion than at 0° flexion. The smallest differences in AP translation between the reconstructed and intact knees were found for the distal femoral placement and 44 N of initial tension applied at 0°. This was not the case for the anterior or posterior femoral attachment locations, for which the 22 N tensioning at 0° and 22 N tensioning at 30°, respectively, produced the least difference when compared to the intact knees. This study demonstrated that there is not a single set of initial conditions that will result in normal knee-joint kinematics, but rather many combinations of initial tension, flexion angle at tensioning, and bone-tunnel location that produce reasonable results. The appropriate initial tension depends on flexion angle, insertion site location, and most likely other mechanical factors, and these may influence graft incorporation and healing after implantation.

**DISCUSSION**

Ideally, allograft ligament reconstruction should restore normal joint kinematics and the restraining role of the compromised ligament. The restoration of normal joint kinematics should prevent future joint degenerative changes and also remove any predisposition to further injury. The new structure should, after a sufficiently long healing and incorporation period, have the same in vivo tension characteristics as the normal structure, and possess size, strength, and stiffness similar to the normal tissue. At this point, the literature is incomplete in reference to graft initial structural and mechanical properties, and the factors that determine the ultimate fate of allograft tissues in vivo are still not completely understood. The latter difficulty can be attributed to factors such as differences between animal models and the human condition, and differing surgical techniques and test protocols. Additional research is needed to clarify the order of events that occur during graft incorporation. Treatment regimens that can potentially improve the result of allograft reconstruction, such as growth factors, must also be investigated. The ability of allograft structures to duplicate the complex mechanical role of the knee ligaments, and thus completely restore normal knee kinematics, is not possible with present methodologies. The surgeon can restore some level of function and approximate the structure’s mechanical role, and thus prevent further injuries and severe degenerative changes.

Strong evidence suggests a mechanosensory role for ligaments in the knee (60). For instance, pulling on ligaments and probing the capsule can trigger neurologic receptors and cause muscle activity. Disruption of ACL has been documented to alter the electromyographic patterns in the gastrocnemius, vastus lateralis, biceps femoris, and semitendinosus (61). It has been suggested that the neural tissues of an injured knee will recover similarly with or without surgical intervention (63). This is one possible explanation for the more or less similar results obtained from surgical and nonsurgical treatment of some knee-ligament injuries. An alternative possibility is that other structures about the knee compensate for ligamentous instability. Ligament reconstruction, with allograft or other tissue, cannot replace neurosensory function in the short term, and the changes in this function over time following reconstruction have yet to be investigated.

The graft initial mechanical properties, fixation method, attachment points onto bones, and the type of tissue and sterilization method used all will have some influence on the outcome of knee-ligament reconstructions. These factors are all controllable by the surgeon, and judicious choice of materials and procedures based on objective evidence of success will be the best guide to successful allograft ligament reconstructions in the knee.

**REFERENCES**


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