Bone-Patellar Tendon-Bone Grafts for Anterior Cruciate Ligament Reconstruction
An in Vitro Comparison of Mechanical Behavior under Failure Tensile Loading and Cyclic Submaximal Tensile Loading

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Background: Secure fixation is an important factor in the success of anterior cruciate ligament reconstruction.
Hypothesis: There is no difference in the mechanical behavior of reconstructions from method of fixation or method of testing.
Study Design: Controlled laboratory study.
Methods: Anterior cruciate ligament reconstructions were performed with bone-patellar tendon-bone grafts in 48 human cadaveric knees. Three different fixation methods (Endobutton, interference screw, suture-post fixation) were compared under failure tensile loading and cyclic submaximal tensile loading.
Results: No difference was observed in ultimate load among the three techniques. Stiffness of the grafts was significantly lower for the suture technique than for the interference screw technique. Cyclic loading revealed significantly different failure rates: 0% of the Endobutton, 38% of the interference screw, and 100% of the suture-post groups. The relative movement of the femoral bone plug and the migration of the bone plug out of the femoral canal were lowest in the interference screw group.
Conclusions: The suture-post fixation is not recommended. The interference screw technique showed the best results, but results were age-dependent, suggesting its best use is in younger patients. The Endobutton technique is recommended for older patients.
Clinical Relevance: Results of testing are useful to the surgeon in making a choice of reconstruction technique.

The success of ACL reconstruction is influenced by several factors. These include the choice of graft, intraarticular placement, graft tensioning, the rehabilitation program, and security of graft fixation. Grana et al.24 determined that the fixation is the weakest link in the early postoperative period until the bone plug of the bone-patellar tendon-bone graft is incorporated. This finding was confirmed in other studies.10,26,38,54 Many different fixation methods are available: metallic5,17,26,29,43 and bioabsorbable5,6,20,30,55 interference screws, buttons,7,21,42,62 fixation posts with cancellous screws,2,18,23,43 staples,4,18,40,49,60 press-fit techniques,29,50,57 and others.1,32,40,42 In their 1987 study of mechanical tests of different fixation methods, Kurosaka et al.35 found that the highest ultimate tensile load was measured for the interference screw. All observed failures occurred at the fixation site.

In most studies, the mechanical properties of the ACL reconstruction are investigated under maximal tensile loading,10 typically as a single overload designed to imitate an injury mechanism.34,38,39,54 However, in vivo, the physiologic loading of the graft is characterized by repetitive submaximal loading. Although many authors refer to the lack of information about graft performance under those cyclic loading conditions,8,13,35,44,46,54 failure ten-
The purpose of this study was to determine the initial mechanical properties (before graft remodeling in vivo) of common fixation methods of bone-patellar tendon-bone grafts for ACL replacement under cyclic submaximal tensile loading and to compare the results with those of common failure tensile tests.

MATERIALS AND METHODS

Specimens

For the study, 48 whole human cadaveric knees (mean age, 45.76 ± 10.6 years; range, 29 to 68; 28 male and 20 female) were available for testing. Knees with pathologic conditions like fractures, tumors, or osteoarthritis were excluded during specimen selection. The knees were harvested within 24 hours after death and stored at −18°C.

The central third of the patellar tendon, 10 mm in width, was prepared by using a ligament stripper. The bone plugs, 25 × 10 mm, were trimmed carefully to fit snugly through a 9-mm cylindrical metal sizing tube. The femur was then prepared for the ACL reconstruction by drilling a hole 10 mm in diameter. The gap size between the bone plug and the drill hole was 1.0 mm in all cases.14 The cortical side of the bone plugs was adjusted in a posterolateral direction.

Fixation Methods

Three different fixation techniques were investigated (Fig. 1): 1) Endobutton (Smith & Nephew, Hamburg, Germany) fixed with one No. 4 Mersilene tape (Ethicon, Norderstedt, Germany); 2) interference screw, 25 × 9 mm (Smith & Nephew); and 3) cancellous screw, 6.5 × 35 mm, with spiked washer (Krauth and Timmermann, Hamburg, Germany) used as post fixation with three No. 5 Ethibond sutures (Ethicon).

The drill hole for the Endobutton was reamed in the fashion that Barrett et al.7 have described previously. For Endobutton fixation, the Mersilene tape was drawn through a 2-mm drill hole in the bone plug and the two inner holes of the button. The Endobutton was pulled through the drill hole and blocked over the lateral condyle.

For the interference screw and suture-post fixation techniques, a 10-mm drill hole was reamed from the intercondylar notch to the anterolateral cortex. For interference screw fixation, the bone plug was pushed into the drill hole, and a K-wire was positioned in the gap at the cancellous bone surface of the femoral bone plug. Then the interference screw was driven, using the K-wire as a guide under protection of the tendon. The knees used for suture-post fixation were fitted with a 5-mm hole in the patellar tendon. The distance between the screw and the lateral exit of the graft drill hole was 10 mm. Three No. 5 Ethibond sutures were drawn through the 2-mm hole in the bone plug and tied over the cancellous screw.

A steel-Kevlar rope (E. I. du Pont de Nemours and Company, Wilmington, Delaware) was attached to the femoral bone plug with a screw anchorage (FASTac Suture Anchor, 2.3 × 4 mm, Arthrex, Naples, Florida) placed 3 mm deep into the bone block near the ligament insertion. The rope was connected to an extensometer (632.12F-20, MTS Systems, Berlin, Germany) for the measurement of the movement between the bone plug and the femur during cyclic testing (Fig. 2). The tibial bone plug was embedded in a ligament clamp using Technovit (Heraeus Kulzer, Wehrheim, Germany). The specimen was kept moist with physiologic saline solution for the duration of preparation and testing.

Test Procedure

A material testing machine (Bionix 858.2, MTS Systems) was used for the experiments. A specially designed jig (Fig. 2) was attached to the machine base to allow adjust-
ment of the femur. The ligament clamp was mounted to the MTS actuator, and the femur was adjusted in an angle of 45° to the piston. A force of 10 N was applied to the bone-patellar tendon-bone complex, and the result was defined as zero length. The failure tensile tests were performed in length-control mode with a speed of 1 mm/sec. Eight samples were tested for each fixation group in the failure tensile tests. The samples were randomly assigned to the different groups.

The cyclic tensile tests were performed in the force-control mode. The samples were loaded cyclically with a sinusoidal load between 30 and 300 N at a frequency of 1 cycle per second up to 60,000 cycles (or until failure). The elongation of the whole femur–bone-patellar tendon-bone complex and the movement of the bone plug with respect to the femur in the direction of the drill hole were recorded at a frequency of 50 Hz for 3 seconds every 600 cycles (Fig. 3). Deformation of the femur was not measured because the change was minimal and not relevant. A special moistening system sprayed saline solution onto the specimen during the whole cyclic submaximal tensile test. Eight samples were tested in each fixation group cyclically. The samples that reached 60,000 cycles without failing were afterward tested in the same way as the failure tensile test specimens.

Before testing, the length of the patellar tendon was measured as a straight line between the midpoints of both bony insertions.

Parameters of Interest

In the failure tensile tests, the following parameters for the femur–bone-patellar tendon-bone complex were determined: ultimate load and load at failure (in newtons); ultimate elongation and elongation at failure (in millimeters); and stiffness and average stiffness (in newtons per millimeter) for the force ranges of 100- to 200-N, 200- to 300-N, 300- to 400-N, and 400- to 500-N loads.

In the cyclic submaximal tensile tests, the following parameters for the femur-bone-patellar tendon-bone complex and the femur–bone plug complex were determined: number of cycles until failure; elongation of the femur–bone-patellar tendon-bone complex (in millimeters) at 600, 20,000, 40,000, and 60,000 cycles; amplitude of the elongation (in millimeters) at 600, 20,000, 40,000, and 60,000 cycles; average stiffness (in newtons per millimeter) for the force ranges of 100- to 200-N and 200- to 300-N loads at 600, 20,000, 40,000, and 60,000 cycles; movement of the bone plug relative to the femur (in millimeters) at 30 N and 300 N at 600, 20,000, 40,000, and 60,000 cycles; and amplitude of the bone plug motion (in millimeters) within a loading cycle at 600, 20,000, 40,000, and 60,000 cycles.

Statistical Analysis

Multifactorial and one-way analyses of variance were calculated with ultimate load, elongation, stiffness, relative motion, and number of cycles until failure as dependent variables. The independent variable investigated was fixation method. Regression analysis was performed between age and ultimate failure load for each fixation method. A chi-square test was performed to check the distribution of sex in the groups. All statistical tests were performed at a probability level of 95% (α = 0.05). Statistics software (SPSS for windows Version 9.0, SPSS, Chicago, Illinois) was used for the analysis.

RESULTS

Failure Tensile Tests

There were no statistically significant differences between the three fixation groups in regard to specimen age (P = 0.54), sex distribution (P = 0.51), or the length of the patellar tendon (P = 0.39) (Table 1). All specimens failed at the femoral fixation site. In seven of eight cases in the
Endobutton group, the Mersilene tape ruptured; in the other case, the tibial bone plug fractured. In the interference screw group, the bone plugs were pulled out of the drill hole in four of eight cases. In the other four cases, the bone plug first fractured close to the ligament insertion and then slipped out of the drill hole. In all of the specimens in the suture-post fixation group, the Ethibond sutures ruptured (Fig. 4).

The ultimate loads were similar for all groups ($P = 0.47$) (Table 1). The ultimate elongation of the specimens in the interference screw group was significantly lower than that of the other two fixation methods ($P = 0.001$) (Table 1), which did not differ significantly. Consequently, the stiffness of the interference screw group for all load levels was significantly greater than that of the Endobutton and the suture-post fixation groups ($P < 0.001$ for all comparisons) (Table 1).

There was no significant correlation between age and ultimate load in the suture-post fixation group ($P = 0.77$), whereas fixations in the Endobutton ($r^2 = 0.53$, $P = 0.039$) and the interference screw groups ($r^2 = 0.65$, $P = 0.015$) showed a significant decrease in failure load with age (Fig. 5).

### Cyclic Submaximal Tensile Tests

There was no statistically significant difference among the fixation groups in the results regarding specimen age ($P = 0.8007$), sex distribution ($P = 0.243$), or the length of the patellar tendon ($P = 0.39$) (Table 1). All samples of the Endobutton group reached the maximum of 60,000 cycles. Three of eight interference screw samples failed before achieving 60,000 cycles. The failures in the interference screw group occurred in the three oldest specimens, all

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**TABLE 1**

Results of Testing of Grafts Fixed with Three Different Techniques

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Endobutton</th>
<th></th>
<th>Interference screw</th>
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<th>Suture-post</th>
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<tr>
<td></td>
<td>$N$</td>
<td>Mean SD</td>
<td>$N$ Mean SD</td>
<td></td>
<td>$N$ Mean SD</td>
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<td>42.3 5.4</td>
<td>8 42.5 5.6</td>
<td>8 45.5 3.8</td>
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<td>Ultimate load (N)</td>
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<td>8 637.3 329.5</td>
<td>8 506.9 104.8</td>
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<td>Ultimate elongation (mm)</td>
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<td>14.3 4.9</td>
<td>8 7.1 2.0</td>
<td>8 12.3 2.6</td>
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<td>Stiffness (N/mm)</td>
<td>100–200 N</td>
<td>8 49.1 16.1</td>
<td>8 113.7 37.6</td>
<td>8 54.0 12.0</td>
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<td></td>
<td>200–300 N</td>
<td>8 43.8 15.4</td>
<td>8 129.2 69.7</td>
<td>8 42.5 12.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>300–400 N</td>
<td>8 44.4 17.8</td>
<td>6 156.9 57.1</td>
<td>7 35.5 7.7</td>
<td></td>
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<td></td>
<td>400–500 N</td>
<td>5 60.5 11.2</td>
<td>4 184.7 46.1</td>
<td>4 45.0 9.5</td>
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<tr>
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<td>8 44.5 6.1</td>
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<td>8 211.1 50.5</td>
<td>6 157.4 37.7</td>
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<td>45.6 3.7</td>
<td>5 44.2 5.1</td>
<td>0 NA NA</td>
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<td>Ultimate elongation (mm)</td>
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<td>5 5.62 0.7</td>
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<td>Stiffness (N/mm)</td>
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<td>5 156.9 17.7</td>
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<td>200–300 N</td>
<td>8 117.7 29.7</td>
<td>5 206.1 21.4</td>
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<td>300–400 N</td>
<td>8 142.0 35.7</td>
<td>5 220.0 27.5</td>
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<td></td>
<td>400–500 N</td>
<td>8 107.3 60.4</td>
<td>5 218.4 32.5</td>
<td>0 NA NA</td>
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</tr>
</tbody>
</table>

**Figure 4.** Left, failure in the Endobutton group with the ruptured Mersilene suture. Middle, a fractured bone plug in the interference screw group. Right, rupture of the Ethibond sutures in the suture-post fixation group.
older than 43 years of age (Fig. 6). In the failure cases, the fixed bone plugs fractured and were then pulled out of the drill hole (Fig. 4). The correlation between failure cycle and age was statistically significant ($r^2 = 0.65$, $P = 0.015$). Ultimate load (interference group) = 1783 N – 21.72 N times age (years), $r^2 = 0.65$, $P = 0.015$. Ultimate load (Endobutton group) = 1013 N – 8.03 N times age (years), $r^2 = 0.53$, $P = 0.039$.

Elongation of the Bone-Patellar Tendon-Bone Complex

After 600 cycles, the elongation of the femur–bone-patellar tendon-bone complex at 30 and 300 N differed significantly among all three fixation methods ($P < 0.001$) (Fig. 7). The elongation at 30- and 300-N loads in the suture-post fixation group was higher than that in the Endobutton group. The elongation at 30- and 300-N loads of the interference screw group was lower than that in both other groups.

With an increasing number of cycles, all samples lengthened slightly (Fig. 7). Because of the early failure of the suture-post fixation, only the Endobutton and the interference-screw fixation techniques can be compared for cycle numbers above 10,000. The same tendency as after 600 cycles was found: significantly lower elongation of the interference screw group when compared with the Endobutton group ($P < 0.001$ for 30 and 300 N after 20,000, 40,000, and 60,000 cycles). The amplitude was significantly higher for the Endobutton group for all cycles investigated ($P = 0.0026$ after 20,000, $P = 0.0068$ after 40,000, and $P = 0.0106$ after 60,000 cycles). Neither the amplitude nor the stiffness of either fixation group increased with test duration (amplitude, Endobutton group, $P = 0.705$; interference screw, $P = 0.6515$; stiffness, Endobutton, $P = 0.7303$, interference screw, $P = 0.9219$) (Table 1).

Motion of the Femoral Bone Plug

The relative motion between the femoral bone plug and the femur after 600 cycles at 30- and 300-N loads was significantly lower in the interference screw group than in the Endobutton fixation and the suture-post fixation group ($P < 0.0001$ for both) (Fig. 8). For the samples of the Endobutton group and the interference screw group, this result corresponded with cycle number ($P < 0.0001$ for 30 and 300 N after 20,000, 40,000, and 60,000 cycles). The bone plug migrated slightly outward from the femoral canal with the increasing number of cycles (Fig. 8).

The amplitude of the relative motion of the femoral bone plug within each cycle showed the same result: highest in the suture-post fixation group, lower in the Endobutton group, and lowest in the interference screw group at cycle 600 ($P = 0.0002$) (Fig. 9). The amplitude did not change with the cycle number for the survivors and was significantly lower for the interference screw group than for the
Failure Tensile Tests after Cyclic Loading

All tested survivors of the cyclic testing (eight Endobutton, five interference screw, and zero suture-post fixation) failed at the femoral fixation side. Rupture of the Mersilene tape caused the failure of the Endobutton group fixations. In the interference screw group, the fixed bone plug fractured in the area of the ligament insertion. The Endobutton samples achieved an ultimate load of 583.75 ± 83.05 N, which was significantly lower than the ultimate load of the interference screw group (837.10 ± 137.37 N, P = 0.0015) (Table 1). There was no correlation between age and ultimate load in the Endobutton group (P = 0.267), whereas the interference screw fixation group showed a negative correlation (r² = 0.94, P = 0.0053) (Fig. 10).

The ultimate elongation of the femur–bone-patellar tendon-bone complex was significantly higher for the Endobutton group than for the interference screw group (P = 0.0093). Consequently, the stiffness of the interference screw group at all load levels was significantly higher than that of the Endobutton group (P < 0.0001 for all load levels).

The comparison of the ultimate loads with and without previous cyclic loading of the samples did not reveal any differences (Endobutton, P = 0.812; interference screw, P = 0.230).

The ultimate elongation after cyclic loading of the samples was significantly lower than that before cyclic loading for the Endobutton group (P = 0.0019) and showed the same tendency for the interference screw group (P = 0.1588). Consequently, the stiffness of the Endobutton and the interference screw fixation increased significantly (Endobutton, 100 to 200 N, P = 0.007; 200 to 300 N, P < 0.0001; 300 to 400 N, P < 0.0001; 400 to 500 N, P = 0.1267; interference, 100 to 200 N, P = 0.0365; 200 to 300 N, P = 0.0374; 300 to 400 N, P = 0.0509; and 400 to 500 N, P = 0.2366) (Table 1).

**DISCUSSION**

The mechanical properties of the bone-patellar tendon-bone complex used for ACL reconstruction were compared under failure tensile and cyclic submaximal loading conditions. The commonly used failure tests only determine the mechanical properties of a graft subjected to a single overload, which may imitate an injury mechanism. Repetitive cyclic submaximal load testing reflects the physiological situation before remodeling of the graft, characterized by a repetitive-force pattern.8,13,44

The in vivo forces sustained by the ACL have been estimated by many authors.22,25,36,37,47,59 A sinusoidal force between 30 and 300 N was used in the cyclic tests, which is in the upper range of the forces that are estimated to occur during normal daily activities. During rehabilitation, the forces are expected to be lower; therefore, the cyclic tests simulate peaks occurring postoperatively before bony ingrowth of the bone plug. The loading frequency was 1 Hz, equal to the frequency of normal walking. The choice of 60,000 cycles reflects a postopera-
tive duration of 1 to 4 weeks (the stage of avascular necrosis of the graft).

In vivo, the ACL reconstruction is loaded during flexion of the knee. In the present study, a flexion angle of 90° was used (corresponding to an angle of 45° between the ACL and the femur). This angle was chosen to simulate the situation of the anterior drawer test.

In the failure tensile tests all specimens failed at the fixation site, as described by many other previous authors. Clinically, most reported failures occur at this location, especially during the first 3 months after surgery when the bone plug of the patellar tendon has not completely grown in.

Many authors have confined their investigations to the failure tensile test for determination of the mechanical properties of the fixation. The values of load failure of the interference screw reportedly range between 235 ± 124 N and 845.8 ± 188.5 N. Differences in test procedure, for example, different speed of tensile loading, screw-specific factors like diameter or length, insertion torque, gap size, and other aspects, substantiate the different results. The failure loads found in the present study fit into the upper range of the values reported in the literature.

Barrett et al. first described the Endobutton technique in 1995, but until now only a few mechanical studies of this method have been published. The ultimate failure load determined in the present study is comparable to the values found by Rowden et al., although fixation and suture techniques were different. The determined ultimate load of the suture-post fixation was higher than that described in the literature because of a difference in suture technique. In the Endobutton and suture-post fixation groups, the sutures were the weakest point and ruptured in the failure tensile tests. The failure tensile test results in this study indicate that all three fixation methods can be recommended equally, if the aspect of failure load alone is considered.

The cyclic test results, however, showed significant differences in failure rate, elongation, and relative movement between the fixation groups. The suture-post fixation method always failed in the cyclic tests, and, therefore, cannot be recommended for clinical use. The different failure rates of the two suture techniques were especially surprising considering the results of the failure tensile tests. Two aspects have to be considered: 1) the mechanical resistance of the No. 4 Mersilene tape to repetitive loading is better than that of the No. 5 Ethibond sutures and 2) the technique itself is responsible. The Mersilene tape is centrally placed in the tunnel by the Endobutton without grazing the bone. In the suture-post fixation technique, the sutures drag along the edge of the drill hole. Although the drill hole was smoothed, the sutures could be damaged by the edge during repetitive loading.

Fixations of the three oldest knee specimens failed by breakage of the bone plug during the cyclic tests of the interference screw fixation. The press-fit mechanism of this fixation method depends on the quality of the bone, which decreases with age. The age dependency of interference screw stability was also confirmed in the failure tensile tests. The Endobutton and the suture-post fixation showed only weak age dependence because the sutures themselves are the weakest link of the complex, not the bone.

The regression lines of the failure tensile test results of the interference screw and the Endobutton cross at an age of 56 years (Fig. 5). After cyclic loading, the regression line of the interference screw group results crosses the mean value of the Endobutton group at an age of 46 years. In the cyclic tests, failures of interference screw fixation occurred in specimens over 43 years of age, indicating that, for patients over 40 to 45 years of age, the Endobutton may be the better fixation technique.

The stiffness of an ACL reconstruction is also an important factor. The stiffness values of the bone-patellar tendon-bone complex in this study were higher than those reported in the literature. Most authors test femorally and tibially fixed ACL reconstructions. In this study the reconstruction was only fitted at the femur; the absence of the second fixation can explain the observed higher values. Furthermore, the cited studies cannot be directly compared unless the loading parameters were the same.

The interference screw group showed a higher stiffness than the groups using the two other techniques, in which the bone plugs are fixed with sutures (Endobutton and suture-post fixation). The sutures were lengthened during loading, and, consequently, the stiffness was lower than in the interference screw group that used the press-fit mechanism.

During cyclic submaximal loading, the bone plug always moved out of the femur, which caused increasing elongation of the whole reconstruction. Because of the lengthening of the sutures or perhaps slippage of the knots, or both, the relative motion of the femoral bone plug in the Endobutton and the suture-post fixation technique was higher. The magnitude of this movement must be viewed critically because a movement of 3 to 5 mm results in a poor postoperative outcome.

Only a few in vitro studies have investigated movement at the fixation site. Paschal et al. reported movements of the femoral bone plug fixed with the interference screw of 0.32 and 2.21 mm for the suture-post fixation. Höher et al. measured the movement of the semitendinosus tendon fixed with the Endobutton and with a No. 5 Mersilene tape in the bone tunnel. They reported a movement of 2.5 mm at a force of 100 N. Unfortunately, they could not separate the elongation of the semitendinosus tendon from that of the Mersilene tape. The present results are near to those of Paschal et al. and Höher et al.; even so, there are differences in the fixation methods, the loading parameters, and the movement assessment.

Movement of the bone plug has also been shown clinically. Friden et al. determined the movement of bone plugs fixed with sutures over buttons and reported a movement of up to 0.7 mm from radiographic measurements obtained 1 year after surgery. Spencer et al. cautioned that the graft could also slip into the joint space.
because of movement at the fixation site. In this respect, the interference screw clearly has advantages over the Endobutton fixation.

The relative motion of the bone plug within a movement cycle is an important factor also. The interference screw group showed the lowest values. The magnitude of the relative motion of the two other fixation techniques may complicate ingrowth of the bone-patellar tendon-bone complex postoperatively. Although Claes et al. demonstrated that movements up to 1 mm do not prevent fracture healing, whether this movement affects ACL reconstruction is still unclear.

Comparison of the movement at the fixation between cycle 600 and cycle 60,000 showed that most of the elongation occurred during the first cycles, underlining the important role of the fixation itself. The comparison of the stiffness determined in the failure tensile tests before and after cyclic loading showed an increase in stiffness of the bone-patellar tendon-bone complex due to the cyclic pre-loading. Consequently, pretensioning may reduce elongation and movement at the fixation site. Yasuda et al. demonstrated an increase of stability 2 years after surgery when a higher pretensioning was used. However, a higher pretensioning may decrease revascularization of the graft and may increase the failure rate. Burks and Leland demonstrated that the optimal pretensioning depends on the type of autograft. The differences in movement found in our study may indicate that the optimal pretension probably also depends on the choice of fixation method.

CONCLUSIONS

The results of determination of the mechanical properties of three different graft fixation methods used in ACL reconstruction indicate that the results of failure tensile and cyclic submaximal tensile tests differ greatly. Both testing conditions must be looked at before one can draw conclusions on clinically relevant mechanical characteristics of different fixation methods. The fixation itself is the weakest link postoperatively, because all failures occurred at the fixation site. The suture-post fixation technique cannot be recommended because it always failed during the cyclic tests. The age of the patient should be considered when making a choice of fixation technique. In patients younger than 40 to 45 years of age, the interference screw is preferable; in older patients the Endobutton technique may offer an advantage.

REFERENCES