= Abstract =

Fixation Strength Analysis of Press-Fit Technique in Anterior Cruciate Ligament Reconstruction using Porcine Lower Limb

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Purpose: The objective of this study was to evaluate the initial fixation strength of press-fit technique compared with titanium and biodegradable interference screws in ACL reconstruction using bone-patellar tendon-bone grafts.

Materials and Methods: Fifty porcine lower limbs were used. The graft in the press-fit group was harvested with a hollow oscillating saw to obtain a consistent and complete circular shape and that in the interference screw group was obtained with a conventional oscillating saw. With preload of 20 N, the specimens underwent 250 loading cycles between 0-2 mm of displacement. Thereafter, the specimens were loaded to failure after restoration of the preload.

Results: During the cyclic loading, none of press-fit or interference screw fixations failed and there was no significant difference in maximum loads between the groups. In groups of press-fit fixation with diameter of bone plug being larger that that of the femoral tunnel by 1.4 mm, the ultimate failure load was comparable with that of the titanium or biodegradable interference screw groups. The complete circular shape and increased diameter of the bone plug seemed to contribute the strong initial fixation.

Conclusion: Press-fit fixation technique provides a secure and consistent fixation strength comparable with the metal or biodegradable interference screws.

Key Words: Knee, Anterior cruciate ligament reconstruction, Press-fit fixation

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INTRODUCTION

The reconstruction of a torn ACL is one of the most common procedures in knee surgery, and various methods of initial graft fixation have been described. The metal interference screw fixation has been one of the most commonly used fixation technique. However, despite of the superior fixation strength there were several disadvantages such as permanent retention of the hardware, diminished pullout strength when the screws are not parallel with the axis of the femoral bone plug, inadvertent graft advancement or laceration of graft or passing suture, and most importantly potential compromise of subsequent surgery and disturbance of postoperative MRI scans. Biodegradable interference screws can provide secure initial fixation comparable with that of metal interference screws while allowing degradation followed by replacement of the host tissue without distortion of MRI scans. However, little is known about the fixation properties of the biodegradable screws within the period while the material is degrading. Other potential problems associated with biodegradable screws are compromised biocompatibility, even though few complications occur in their clinical use, including severe foreign body reaction, and synovial reaction.

The problems related to the interference screws mentioned above gave impetus to develop other fixation methods and the press-fit technique came about in an attempt to do away with these difficulties, without compromising fixation strength or prolonging the patient's rehabilitation. The bone plug with slight larger diameter than that of the femoral tunnel is wedged into the femoral tunnel in this method. The absence of any fixation device enables a clear MRI scans and may avoid fixation device related problems. However, the fixation strength of the press-fit technique may be the most worrisome point of this method.

The objective of this in vitro study on porcine limbs was to evaluate the initial fixation strength of the press-fit technique in which we attempt to improve the fixation strength by increasing the diameter of bone plug and harvesting the bone plug in complete circular shape with a hollow oscillating saw. We compared the fixation strength of the press-fit technique with that of titanium and biodegradable interference screws, especially under the conditions simulating the postoperative rehabilitation period.

MATERIALS AND METHODS

Fifty porcine knees from pigs weighing 80-100 Kg and of average age 6-8 months were used. They were harvested immediately after death (<4 hours), all soft tissues were removed, and the specimens were frozen at -20°C. The specimens were thawed at room temperature for 12 hours before testing. Every patella and femur was submitted to bone mineral density (BMD) evaluation by dual-energy x-ray absorptiometry scans (Lunar Expert #1161, Lunar Radiation Corp., Madison, Wisconsin, USA).

The specimens were randomly assigned to one of five groups according to the ways of fixation of the bone plug to the femoral tunnel: group 1 (N=10), press-fit...
fixation group in which diameter of the bone plug was 1 mm larger than that of the femoral tunnel; group 2 (N=10), press-fit fixation group in which diameter of the bone plug was 1.4 mm larger than that of the femoral tunnel; group 3 (N=10), titanium interference screws group (7x20 mm, Linvatec Co., Largo, Florida, USA); group 4 (N=10), biodegradable interference screws group (7x20 mm, Linvatec Co., Largo, Florida, USA); and group 5 (N=10), press-fit fixation group in which diameter of the bone plug was 1.4 mm larger than that of the femoral tunnel and the angle between loading axis and the femoral tunnel axis was 30°.

Technique for fixation of bone-patellar tendon graft

The patellar tendon of every specimen was carefully dissected in continuity with the patellar bone plug, leaving the tibial insertion site intact. For group 1, 2, and 5, a 9.4 mm oscillating hollow drill was used to harvest patellar bone plug. In this manner, a bone plug from patella with standardized cylindrical bone plugs of 9.4 mm in diameter and 20 mm in length was harvested (Fig. 1). Especially for group 1, bone plugs were trimmed circumferentially to a diameter of 9.0 mm which were checked precisely by sizing block. The tip of the plug was reduced to a smaller diameter to guarantee a safe entrance of the plug into the 8 mm bone tunnel. For group 2, and 3, the bone plug was standardized to 8x8x20 mm with a conventional oscillating saw. Patellar tendon was harvested in width of 9 mm in each group. A femoral tunnel of 8 mm diameter and 20 mm length was made at the original femoral attachment site of ACL anterior to the posterior femoral cortex.

The prepared patellar bone plug was inserted into the femoral tunnel in each specimen with the cancellous surface oriented anteriorly and flush with the...
intraarticular edge of the femoral tunnel in all specimens. For group 1, 2, and 5, the bone plug was driven into the tunnel with an impactor and a mallet gently and carefully (Fig. 2). For group 3, 4, to facilitate parallel screw-bone block placement, a guide wire was inserted along the bone plug parallel to the long axis of the femoral tunnel. An interference screw was inserted over the guide wire. The screw was advanced until flush with the edge of the bone block.

Mechanical testing

After insertion of the screw, the specimens were mounted in the tensiometer (Instron 8511, Instron Corp., Canton, MA, USA). In group 1, 2, 3, and 4, to fix the specimen to the tensiometer, the femur was potted in a box with PMMA resin so that the femoral tunnel would be vertical to the ground and then mounted with the custom-made serrated clamp attached to the tensiometer. The orientation of the applied load was vertical to the ground and parallel to the long axis of the bone plug and the femoral tunnel (Fig. 3). In group 5, the femur was potted so that the divergent angle between the load axis and the femoral tunnel could be 30°. Then, tibia was also mounted vertical to the ground with the custom-made serrated clamp. The specimens were kept moist with saline during all testing. A preload of 20 N was applied.

In the first step, all specimens underwent 250 load cycles with a speed of 0.2 Hz between 0-2 mm of displacement. Analysis for slippage of the bone plug was done visually. The load-displacement curve was recorded and the maximum load during cyclic load was calculated. In the second step, a vertical tensile load was applied at a rate of 50 mm/min until failure after restoring the preload of 20 N. Again the load-displacement curve was obtained and the linear load, the ultimate failure load, and the stiffness was calculated. The linear load was defined to be the load at the point of first significant failure following the initial toe region. This load signified the approximate point at which the ligament preparation enters into the major failure region. The ultimate failure load was defined to be the maximum load in the curve. The slope of the curve in the linear region was termed the stiffness. Failure mode was demonstrated by visual analysis.

Statistical analysis

Mann-Whitney U test and one way-ANOVA were performed. Significant variables in one way-ANOVA were verified by Duncan multiple comparison method. SPSS version 10.0 was used for this purpose.

Fig. 3. The diagram of the mechanical test. The load axis is parallel to the femoral tunnel in bone (A) anteroposterior view, and (B) lateral view.
RESULTS

Bone mineral density

The results of bone mineral density were illustrated in (Table 1). There was no statistically significant difference in both of femur and patella among the groups.

Cyclic loading test

None of the specimens in any group showed slippage during cyclic loading and there was no statistically significant difference in average maximum load among groups.

Load to failure test

The mean linear load was 358.1 N for group 1, 541.4 N for group 2, 676.1 N for group 3, 700.9 N for group 4, and 593.0 N for group 5 (Table 2). The linear load was significantly lower in group 1 than in the other groups and was also significantly lower in group 2 than in group 3 and 4 when compared directly using Mann-Whitney test (p < 0.05). But, there was no statistically significant difference among group 3, 4 and 5 (p > 0.05). While, using Duncan multiple comparison test after One-way ANOVA, only the linear load of group 1 was significantly lower than that of other groups (p < 0.05). This confusion may be resulted from a relatively small sample size.

In case of the ultimate failure strength, that of group 4 was highest. The ultimate

Table 1. Bone mineral density (g/cm²)

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Femur</th>
<th>Patella</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (press-fit+1 mm)</td>
<td>0.663±0.139</td>
<td>0.555±0.077</td>
</tr>
<tr>
<td>Group 2 (press-fit+1.4 mm)</td>
<td>0.646±0.114</td>
<td>0.591±0.091</td>
</tr>
<tr>
<td>Group 3 (titanium screw)</td>
<td>0.621±0.151</td>
<td>0.614±0.074</td>
</tr>
<tr>
<td>Group 4 (bioabsorb. Screw*)</td>
<td>0.661±0.105</td>
<td>0.553±0.097</td>
</tr>
<tr>
<td>Group 5 (press-fit+1.4 mm&amp;30°)</td>
<td>0.682±0.149</td>
<td>0.616±0.100</td>
</tr>
</tbody>
</table>

Table 2. Results of mechanical test (N)

<table>
<thead>
<tr>
<th>Fixation</th>
<th>Maximum cyclic load</th>
<th>Linear load</th>
<th>Ultimate failure load</th>
<th>Strain (N/mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (press-fit+1 mm)</td>
<td>172.60±48.88</td>
<td>358.10±104.69</td>
<td>366.60±106.73²</td>
<td>118.89±29.56</td>
</tr>
<tr>
<td>Group 2 (press-fit+1.4 mm)</td>
<td>168.10±41.63</td>
<td>541.40±72.11</td>
<td>571.40±108.78</td>
<td>125.79±29.44</td>
</tr>
<tr>
<td>Group 3 (titanium screw)</td>
<td>173.60±47.83</td>
<td>676.10±139.91</td>
<td>691.10±146.26</td>
<td>107.09±24.86</td>
</tr>
<tr>
<td>Group 4 (bioabsorb. Screw*)</td>
<td>173.60±41.84</td>
<td>700.90±164.34</td>
<td>707.40±169.08</td>
<td>115.29±25.70</td>
</tr>
<tr>
<td>Group 5 (press-fit+1.4 mm&amp;30°)</td>
<td>153.90±33.89</td>
<td>593.90±100.18</td>
<td>605.40±91.57</td>
<td>108.26±24.92</td>
</tr>
</tbody>
</table>

a: Significant difference compared to the other groups tested by Mann±Whitney test (p < 0.05)
b: Significant difference compared to group 3, 4, and 5 tested by Mann±Whitney test (p < 0.05)
c: Significant difference tested by One-way ANOVA test (p < 0.05)
failure strength was significantly lower in group 1 than in other groups and there was no significant different among the other groups when verified by both Mann-Whitney test and One-way ANOVA (p < 0.05).

The stiffness was not significantly different among all the groups.

Failure mode

The analysis of the failure modes showed that all specimens failed at the fixation site. In group 1, eight were pulled out of the tunnel, two were failed at the bone-tendon junction. Six were pulled out of the tunnel and four failures occurred at the bone-tendon junction in group 2. In group 3, 4, and 5, pullout occurred in nine, seven, and four cases respectively, and the bone-tendon junction rupture occurred in one, three, and four cases respectively.

DISCUSSION

There are several factors that influence the fixation strength such as donor age and bone quality, tissue type, fixation technique, shape of the graft and etc. Bone mineral density is well known to be an important factor for determining the fixation strength. An osteoporotic bone block and a week bony tunnel from an older donor is less desirable providing poor bone end and inadequate fixation bed. If bone strength is reduced, the ability of the fixation method to anchor the graft is also reduced. It is crucial that bone quality should be the same for each group being tested for a comparative biomechanical study of fixation strength. The investigators should try to match specimens as closely as possible to equalize the factors influencing the strength of fixation. The use of porcine specimens with almost same age and weight could help to control specimen-related bias.

In 1993, Paschal et al noted the mean ultimate failure load of interference fixation using 9.0 mm cannulated Kurosaka screws in skeletally mature porcine bone was comparable with that of young human bone (average age, 22 years) and significantly greater than that of older human bone (average age, 60) in static loading test and that could provide meaningful data for clinical practice. From this point of view, there seems to exist no substantial difference between porcine and human bone with respect to ultimate strength of the interference screw fixation. For these reasons, we used a homogenous group of porcine knees with nearly identical age and weight to control specimen-related bias. In our experiment, there was no significant difference in both of femoral and patellar bone mineral densities among the groups.

Previous studies regarding the initial fixation strength of the press-fit fixation technique showed somewhat disappointing results. In 1997, Rupp et al reported the pullout strength of a press-fit technique. They drilled a 10 mm diameter hole in the tibia and harvested a bone plug with a diameter of 11 mm from patella in semicircular shape. The ultimate failure load was significantly lower than that of the biodegradable screws and the titanium screws. In 1998, Seil et al added cyclic loads to conventional load-to-failure type of mechanical test. However, they were supposed to obtain a bone plug with a conventional sagittal saw and
trimmed it to a semicircular shape with a diameter of 11 mm. This relatively incomplete circular shape would not provide as snugly fit as one of complete circular shape and this might result in decreased fixation strength. In addition, bone plug diameter of 11 mm would not be sufficiently large for strong fixation compared with bone tunnel diameter of 10 mm.

In 1992, Shapiro et al reported that circular bone plugs, obtained with a circular oscillating saw provided 19.9% greater pullout strength compared with identically fixed trapezoidal bone plugs and that circular defects have 107% greater strength than that of matched trapezoidal patellar defects in three-point bending\(^2\). In this study, we hypothesized that the more snugly fitted a bone plug with complete circular shape and increased diameter would result in the stronger fixation strength. We used a hollow oscillating saw which enabled a precise and consistent bone plug and increased the diameter difference between the bone plug and the femoral tunnel from usual 1 mm to 1.4 mm to improve the fixation strength.

It is well known that graft fixation site is the weakest link during the first few weeks. It is a prerequisite for a graft fixation method to provide a sufficient primary stability to allow for an aggressive rehabilitation protocol for routine daily activities. While no direct in vivo measurements exist on these functional loads during daily activities, it has been estimated approximately 500 N\(^6\).\(^{10}\). Considering the resultant loads in accelerated rehabilitation which is reported up to 200 N, the fixation strength must be minimum of 200 N during the rehabilitation period and reasonably 500 N for routine daily activities\(^7\).\(^9\).\(^{10}\). In the present study, the linear load and ultimate failure load of group 1 (the diameter difference of 1 mm) were average 358.10±104.69 and 366.60±106.73 N which could be considered adequate for accelerated rehabilitation but not for daily activities. But in group 2 (the diameter difference of 1.4 mm), the linear load and the ultimate failure load were average of 541.40 N and 571.40 N respectively which could be regarded sufficient for both rehabilitation and daily activities and it should also be noted that the ultimate failure load was not significantly different from that of a titanium screw (group 3, 691.10±146.26 N) and that of a biodegradable screw (group 4, 707.40±169.08 N). In addition, in group 5 where the load was pulled 30° divergent to the femoral tunnel axis, both of the linear load and the ultimate failure load were not significantly different from those of titanium screws and biodegradable screws.

In the first step of the present study, we loaded the graft 250 times repeatedly in an attempt to duplicate the physiologic loading conditions of the graft during rehabilitation. And then, the graft was loaded to failure for determining the ultimate failure load after restoration of preload. After ACL reconstruction, the graft is loaded repeatedly in a certain range of elongation during rehabilitation such as continuous passive motion or walking rather than loaded to a certain level of force. For that reason, we chose the method of controlling the maximum elongation placed on the graft during each cycle rather than controlling the maximum force in cyclic loading. The magnitude of elongation was 2 mm which is
generally accepted graft motion in ACL reconstruction.

We arbitrarily chose the displacement rate of 50 mm/min, and this rate was quite frequently used by several authors\(^1\),\(^{16}\),\(^{23}\),\(^{25}\). It is not known whether using different strain rate would significantly alter the findings of this study. In 1977, Kenney et al reported roughly equal strengths at maximum load in both the ACL and the tibial collateral ligament tested at 12.5 (7% per second) and 50 cm/min (28% per second)\(^{14}\). In 1994, Blevins et al reported tensile strength, modulus, and failure mode were not significantly different for tests conducted at 10% or 100% elongation per second using human bone-patellar tendon-bone graft\(^3\). But in 1998, Yamamoto and Hayashi reported a conflict result using rabbit patellar tendon in wider range of the strain rate\(^{27}\). They found that the tensile strength and strain at failure of the tendon increased by 51% and 77%, respectively with increase in the displacement rate from 0.33 mm per second to 560 mm per second (from 0.566% per second to 1250% per second). The strain rate of about 2% per second which we used is relatively slow and may represent a slow-velocity injury during early postoperative rehabilitation.

In conclusion, the fixation strength of the press-fitted complete circular shape of bone plug with diameter difference of 1.4 mm may be sufficient during the time needed for incorporation of the graft.

REFERENCES

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