Comparative biomechanical study of the Ligament Plate® and other fixation devices in ACL reconstruction

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Abstract The objective of this study was to evaluate and compare the biomechanical properties of the Ligament Plate® with other femoral fixation devices. The Ligament Plate® and three different femoral fixation devices were used in fixation of 60 porcine femora and harvested porcine tendons. For each fixation device, a porcine graft-tendon complex was used for the simple load-to-failure test and the load-to-failure test after a cyclic loading test, and the maximal failure load was measured. The amount of graft elongation and failure pattern after the cyclic loading test and load-to-failure test were evaluated. In the BioScrew® group, the mean maximal failure load in the load-to-failure test and load-to-failure test after a cyclic loading test was significantly lower and significant graft elongation was noted. There were no significant differences between the other groups. The Ligament Plate® provided adequate initial fixation power suitable for early rehabilitation.

Résumé L'objectif de cette étude est d'évaluer et de comparer les propriétés biomécaniques du ligament plaque® avec d'autres systèmes de fixation fémorale. Matériel et méthode: le ligament plaque et différents matériels de fixation fémorale ont été utilisés dans le traitement des fractures fémorales chez le porc. Pour chaque matériel de fixation la greffe tendineuse de porc a été testée en charge jusqu'à la rupture avec élancement de la greffe et test cyclique de rupture en charge. Résultats: Dans le groupe Bioscrew les tests en charge sont moins bons, néanmoins, il n'y a pas de différence significative dans les deux groupes. En conclusion: le

ligament Plaque permet d'avoir une bonne fixation initiale et permet une réhabilitation précoce.

Introduction

Recently, with the change to a modern lifestyle of people and the increase in sporting activities, anterior cruciate ligament (ACL) injuries have increased and ACL reconstruction is one of the most successful treatments showing an approximately 70–90% success rate [1, 12]. The grafts used in ACL reconstruction include bone-patella tendon-bone (BPTB), hamstring tendon, quadriceps tendon and allograft, etc. The grafts most commonly used are the BPTB and hamstring tendon. With the technical improvement of the femoral fixation devices the use of hamstring tendons in ACL reconstruction is on the rise [6]. In this study, the Ligament Plate® (Solco Biomedical, Seoul, Korea) was developed as a femoral fixation device that can provide adequate early fixation strength, and the usefulness of the Ligament Plate® was evaluated through biomechanical comparative studies with other fixation devices.

Materials and methods

Sixty porcine femora and the harvested porcine third and fourth extensor digitorum tendons were used for the experiment. The pigs were of both genders, approximately six months old, and weighed approximately 100 kg. After measuring the bone density, the porcine femora were stored with the harvested tendons in a freezer lower than −70°C.

On the day of the experiments, the porcine femora and the harvested tendons were thawed completely for a few

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hours at room temperature, and the harvested porcine tendons were prepared in a quadrupled manner. The femoral tunnel was made from the original ACL insertion site of the femur in the direction of the lateral ridge of the distal femur. The length of the tunnel was at least 3 cm and the diameter was determined by the size of the harvested graft. The prepared grafts were fixed on the femora using four different fixation devices. To prevent a mismatch between the tunnel and the grafts, the diameters of the prepared grafts were measured in advance, and bone reamers fitted to the size were used.

For the simple load-to-failure test, the prepared grafts were fixed to the interlocking grip of the 858 Tabletop System® (MTS Systems Corporation, Eden Prairie, MN, USA) as the direction of traction was identical to the axis of the femoral tunnel. For the cyclic load-to-failure test, similar to the normal knee joint, it was fixed to the interlocking grip and the pullout strength was measured along the direction vertical to the knee joint (Fig. 1). The power of the interlocking grip was approximately 10 MPa. At that time, the length of the grafts from the entrance of the femoral tunnel to the interlocking grip on the tibial side was maintained as approximately 3 cm apart. Four different types of fixation devices, the EndoButton® (group 1, Smith & Nephew, Andover, MA, USA), the TransFix® (group 2, Arthrex, Naples, FL, USA), the BioScrew® (group 3, Linvatec, Largo, FL, USA) and the Ligament Plate® (group 4, Solco Biomedical, Seoul, Korea), were used (Fig. 2). The prepared porcine graft was fixed in the lateral femoral condyle with each device according to the recommendations of the manufacturer. The Ligament Plate® is made of

a titanium-based alloy and has a U-shaped body for graft suspension and two wings which contain screw holes to allow secure femoral fixation with the screw (Fig. 3). The technique for fixing the Ligament Plate® was as follows. After placing the femoral guide at the anatomical attachment site of the ACL in an outside-in manner, the femoral tunnel was dilated by the cannulated reamer according to the diameter of the porcine graft. The prepared graft was suspended on the Ligament Plate® and passed through the tunnel from the lateral femoral cortex. The Ligament Plate® was fixed with screws on the lateral cortex of the femur.

For each fixation device, five graft-femur complexes were used for the simple load-to-failure test, maintaining the constant speed of approximately 50 mm/min in the direction identical to the axis of the femoral tunnel, and the data were recorded on a computed recorder. The maximum failure load was measured, and the pattern of failure was analysed. For the cyclic load-to-failure test, ten samples were used for each fixation device. Before the test, a preload identical to the simple load-to-failure test was applied (50 N, 30 s) in order to prevent the failure caused by sudden load during the load-to-failure test, and the applied load was increased from 50 to 250 N by computer programmed loading, and the cyclic load-to-failure test was performed 1,500 times. The load was applied in the direction vertical to the joint which is similar to the normal anterior cruciate ligament. The amount of load, the cycles, the amount of elongation of the graft and the amount of slippage from the fixation location were recorded in a computed recorder, and in failed cases the pattern of failure was analysed.

Fig. 1 The testing apparatus using the 858 Tabletop System® is shown with porcine femora and grafts

Fig. 2 The implants are from left to right: EndoButton®, TransFix®, BioScrew®, and Ligament Plate®

The simple load-to-failure test after the cyclic load-to-failure test was performed only on the preserved tendons from the cyclic load-to-failure test, the result was recorded in a computed recorder and the maximal failure load was measured, and in failed cases the failure patterns were analysed. The amount of graft elongation was measured after the cyclic load-to-failure test and simple load-to-failure test after the cyclic load-to-failure test. For statistical analysis, the results were compared using the Kruskal-Wallis test with the Statistical Package for the Social Sciences (SPSS Version 11), and the result of each group was compared using the Mann-Whitney test. Significance was set at $P < 0.05$.

Results

The simple load-to-failure test

The mean maximal failure load in groups 1, 2, 3 and 4 was 989.7 ± 70.2 N (877.6 – $1,067.5$ N), $1,072.5 \pm 132.9$ N (899.7 – $1,205.1$ N), 439.4 ± 76.2 N (360.7 – 561.9 N) and $1,011.3 \pm 100.5$ N (867.3 – $1,111.2$ N), respectively ($P_K = 0.010$, P_K : P value of the Kruskal-Wallis test). The maximal failure load was significantly lower in group 3 than in the other groups. On the other hand, there was no significant

difference between the other groups (Fig. 4, $P_M = 0.009$, P_M : P value of the Mann-Whitney test).

The simple load-to-failure test after the cyclic load-to-failure test

In one case from group 3, during the cyclic load-to-failure test, pullout failure occurred due to destruction of the fixation device. Excluding that case, in 39 cases from all groups, the mean maximal failure load of groups 1, 2, 3 and 4 was 858.5 ± 133.6 N (721.1 – $1,088.6$ N), 896.7 ± 137.6 N (731.9 – $1,178.9$ N), 365.9 ± 70.8 N (250.9 – 471.6 N) and 908.5 ± 104.4 N (743.9 – $1,048.7$ N), respectively ($P_K = 0.000$). The mean maximal failure load was significantly lower in group 3, but there was no difference between the other groups (Fig. 4, $P_M = 0.000$).

The amount of graft elongation

After performing the cyclic load-to-failure test, the mean level of graft elongation in groups 1, 2, 3 and 4 was 1.1 ± 0.2 mm (0.9 – 1.4 mm), 1.0 ± 0.1 mm (0.9 – 1.3 mm), 1.2 ± 0.2 mm (0.9 – 1.4 mm) and 1.1 ± 0.2 mm (0.9 – 1.3 mm), respectively ($P_K = 0.095$). There was no significant difference between the groups ($P_M > 0.05$). Regarding the amount of elongation in the simple load-to-failure test after the cyclic load-to-failure test, the mean amount of graft elongation in groups 1, 2, 3 and 4 were 5.2 ± 1.0 mm (3.6 – 6.3 mm), 3.4 ± 0.8 mm (2.5 – 4.7 mm), 10.1 ± 3.1 mm (6.5 – 13.9 mm) and 3.6 ± 0.7 mm (2.5 – 4.3 mm), respectively ($P_K = 0.002$). Significant graft elongation was noted in group 3. However, there was no significant difference between the other groups (Fig. 5, $P_M = 0.009$).

Failure patterns

Regarding the failure patterns, nine cases in group 1 showed graft rupture in the interlocking grip and there was one case of a deformed fixation device in the femoral cortex. The grafts in all cases in group 2 ruptured in the interlocking grip; in group 3, five cases showed graft rupture in the interlocking grip, failure of pulling the graft was observed in two cases, rupture of the graft in the fixation area was observed in two cases and destruction of the fixation device itself was shown in one case. In group 4, all cases showed graft rupture in the interlocking grip (Table 1).

Discussion

One of the important factors determining the prognosis after ACL reconstruction is early rehabilitation, and for success-

Fig. 3 The Ligament Plate® (Solco Biomedical, Seoul, Korea)

Fig. 4 Results of cyclic loading and load-to-failure test series (*A*: failure load before cyclic loading, *B*: failure load after cyclic loading)

ful early rehabilitation, fixation strength of the graft is the most important factor [3, 6, 18].

The early fixation strength of the BPTB is superior to the hamstring tendon and allows early rehabilitation; therefore, it is considered for young people, athletes, etc. However, if the BPTB is chosen as graft, anterior knee pain, injury of the extensor mechanism or patella fracture could develop as a complication [1, 4]. In contrast, hamstring tendons have the advantages that they cause less anterior knee pain, less donor site morbidity and offer good revascularisation and preservation of the extensor mechanism. However, hamstring tendons have a shortcoming in that the initial fixation strength is weak, making it difficult to perform an early rehabilitation programme [10].

In biomechanical studies, the maximal biomechanical strength of the normal ACL has been shown to be $1,725 \pm 268$ N, the semitendinosus tendon was $1,216 \pm 50$ N and the gracilis tendon was 838 ± 30 N, and received 454 N loading in most daily activities [21]. Handle et al. [11] compared the biomechanical properties of an original ACL, BPTB and hamstring tendon. They reported that the original ACL showed a maximum average load of $1,246 \pm 243$ N in the

section area of about 30 mm^2 , the BPTB showed values of $3,855 \pm 550$ N in the section area of 80 mm^2 , the gracilis tendons showed values of 925 ± 127 N in the section area of 10 mm^2 and the semitendinosus yielded a result of $2,050 \pm 159$ N in the area of 20 mm^2 . Regarding maximal biomechanical strength of porcine tendons, Milano et al. [19] reported $1,987 \pm 347.7$ N in doubled porcine tendons. Nurmi et al. [20] reported in a comparative study of pigs and human cadavers an approximately 30% difference in porcine cases, and Magen et al. [17] reported that porcine tendons were so weak as to be half that of human tendons, could not provide sufficient strength and were not suitable as research subjects.

However, in our study, the maximal biomechanical strength using the quadruple third and fourth porcine common extensor tendons was $1,021 \pm 32$ N, and it was sufficient to replace hamstring tendons. Milano et al. [19] reported three different fixation mechanisms for the femoral fixation of an ACL graft, which they classified into compression, expansion and suspension. The suspensory devices were further divided into cortical, cancellous, and cortical-cancellous mechanisms. In cases using the EndoButton®, as the cortical

Fig. 5 Results of cyclic loading and load-to-failure test series (*A*: elongation after cyclic loading, *B*: elongation after simple cyclic loading)

Table 1 Failure patterns

Group	Graft tear on clamp site	Graft tear on device site	Graft pullout	Hardware deformation	Hardware breakdown
EndoButton	9			1	
TransFix	10				
BioScrew	5	2	2		1
Ligament Plate	10				

suspensory device, even though high fixation strength can be obtained, a very low stiffness in comparison to the normal ACL or BPTB was shown [23] and due to a bungee effect, the result of the long distances between the fixation sites and elastic materials, the widening of femoral tunnels would be expected [9, 13, 15]. In cases using cross-pins, as the cortical-cancellous suspensory devices, excellent strength and stiffness have been reported [8]; nonetheless, it has the shortcomings of bungee effects and slippage within cancellous bones [14]. Interference screws, as the compression fixation devices, could be fixed close to the normal ACL attachment site [22], and additional incisions are not required. In cases when bioabsorbable screws are used, it has an advantage that it does not distort the results of magnetic resonance imaging; however, in comparison with cases using the BPTB, it showed remarkably low strength and stiffness [2] and it may induce an inflammatory reaction [5, 16].

The Ligament Plate[®], which can be classified as a cortical suspensory device, could be fixed on the cortical bone with a screw in comparison with the BioScrew[®] which is fixed in the aperture. It has high fixation strength and can prevent slippage, and compared to the TransFix[®] fixed in the cancellous bone, it can be used in osteoporotic cases due to the two wings of the Ligament Plate[®] (Fig. 3). Also, in comparison with the EndoButton[®], the distance to the fixation site is shorter in cases when the Ligament Plate[®] is used because the graft protrudes into the femoral tunnels from the lateral femoral cortex. The short distance to the fixation site of the Ligament Plate[®] might have a role in reducing the bungee effect. In the BioScrew[®] group, regarding the maximal failure load in the simple load-to-failure test and the simple load-to-failure test after the cyclic load-to-failure test, Kousa et al. [14] reported 589 ± 204 N and 565 ± 137 N, respectively, and Milano et al. [19] reported the simple load-to-failure test after the cyclic load-to-failure test as 407.2 ± 145.4 N. In the EndoButton[®] group, Kousa et al. [14] reported $1,086 \pm 185$ N and 781 ± 252 N, respectively, and Milano et al. [19] reported the simple load-to-failure test after the cyclic load-to-failure test as 850.0 ± 189.8 N. In the TransFix[®] group, Milano et al. [19] reported the simple load-to-failure test after the cyclic

load-to-failure test as $1,469.7 \pm 315.5$ N. The results of these studies showed that the maximal failure load of the suspensory fixation device was higher than the aperture fixation device in the simple load-to-failure test and simple load-to-failure test after the cyclic load-to-failure test. However, there was no difference depending on the type of suspensory fixation devices. In studies with porcine bones, Nurmi et al. [20] reported that the trabecular bone density of the porcine tibia was significantly higher than that of humans as assessed by peripheral quantitative computed tomography (CT) scan. The bone density of the porcine tibia was 323 ± 41 mg/cm³, and the bone density of the human tibia was 177 ± 32 mg/cm³. Chang et al. [7] reported that on dual-energy X-ray absorptiometry, the bone density of the porcine tibia was on average 1.20 g/cm² (0.92 – 1.30 g/cm²) and was identical to that of a young human. In our study, similarly, the bone density of the porcine femur showed an average of 1.498 ± 0.141 g/cm² (1.381 – 1.750 g/cm²), which was higher than that of a human, and it is considered that the porcine femur provided sufficient bony support to the BioScrew[®]. Thus, it is believed that the BioScrew[®] might have the possibility of damaging the graft.

Our study has several limitations. First, we performed this study with porcine bone and ligaments due to the limited availability of human cadavers. Although the porcine femur has sufficient bone density comparable to that of a human, we believe that cadavers of young humans are better substitutes for experiments. Second, the direction of loading applied in a porcine femur-ligament complex cannot reflect the exact human knee kinematics.

Conclusion

The Ligament Plate[®] did not show a significant difference from the EndoButton[®] and the TransFix[®], and it provided adequate initial fixation power suitable for early rehabilitation. However, the BioScrew[®] showed notably inferior results in the simple as well as the cyclic load-to-failure tests and the amount of graft elongation, too. Caution is required for use in clinical applications.

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