



Supplementary tibial fixation in anterior cruciate ligament reconstruction – Direct cortical fixation using spiked washer screw vs. post-tie using washer screw

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We compare clinical outcomes of two different supplementary tibial fixation in anterior cruciate ligament (ACL) reconstruction using free tendon Achilles allograft. Eighty subjects underwent ACL reconstruction using Endobutton CL for femoral fixation and Bio-interference screw for tibial fixation. Supplementary tibial fixation was performed as direct cortical fixation using spiked washer screw (group I) or as post-tie using washer screw (group II). Lachman test, pivot shift test, IKDC classification, Lysholm score, and side-to-side difference (SSD) were evaluated. Thirty six in group I and thirty five in group II could follow up for at least 2 years. At the last follow-up, 7 in group I and 1 in group II showed 2+ or 3+ in Lachman test ($p = 0.027$). Mean SSD was 2.4mm in group I and 1.4mm in group II ($p = 0.048$). Post-tie using washer screw was more effective than direct cortical fixation using spiked washer screw to restore stability.

Level of evidence : Therapeutic Level I ; Randomized controlled clinical trial.

Keywords : anterior ; cruciate ; ligament ; reconstruction ; Achilles ; post-tie ; spiked washer.

INTRODUCTION

As incidence of anterior cruciate ligament (ACL) injury increases, the number of reconstruction of ACL rapidly increases as well. Bone-patellar ten-

don-bone graft has been widely used, however, usage of Achilles tendon allograft gradually increases due to concerns over morbidity at donor site. In the past, the outcomes of bone-to-bone fixation were better than those of soft tissue-to-bone fixation, however, the outcomes of ACL reconstruction using soft tissue graft have been improved with development of technology and technique of fixation through biomechanical studies (12,9,24). Pullout strength at metaphyseal bone in tibia has been reported less than that in femur from many biomechanical studies (25). The reasons are that the bony structure of the tibial metaphysis is less dense

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than that of the femoral metaphysis and that the direction of pullout force of the graft is parallel to the tibial tunnel, while it is usually angled to the femoral tunnel (5,6,14). The softer cancellous bone in the tibia impairs the grip of fixation devices that primarily engage cancellous bone, such as the interference screw (7). Poor fixation may increase the chance of residual laxity and often lead to unsatisfactory outcomes of operation. Sufficient stiffness of graft fixation allows early mobilization and lessens the residual laxity (23). In tibial tunnel, soft tissue grafts are usually fixed with interference screw and staple or spiked washer screw is often used for supplementary fixation on tibial cortex to improve stiffness of the graft construct (13,30,26). These additional fixations often cause problems due to considerable profile at fixation site and irritation of soft tissue coverage especially with spiked washer screw or staple. Furthermore, there may also remain the residual laxity even with the supplementation. The purpose of this study was to compare the clinical outcomes of two different supplementary fixation methodology in ACL reconstruction using free tendon Achilles allograft with biodegradable interference screw in the tibial tunnel ; direct cortical fixation using spiked washer screw versus post-tie using washer screw. The null hypothesis of this study was that the clinical outcomes of the ACL reconstruction with supplementary tibial fixation were not significantly different between two groups ; direct cortical fixation with spiked washer screw versus post-tie fixation with washer screw.

MATERIALS AND METHODS

Subjects

A prospective, randomized, comparative study was conducted with the approval of ethics committee of our institution during June 2009 to April 2011. A total of 130 subjects were diagnosed with ACL injuries. Subjects who had medial collateral ligament injury which had been treated conservatively or meniscus tear which was managed by partial meniscectomy were included. Subjects who had meniscus repair, subtotal or total meniscectomy, other ligament injuries which need surgeries other than ACL, any injury on ipsilateral leg other than knee, previous injury on contralateral leg, and full thick-

ness cartilage damage which needs microfracture, multiple drilling, osteochondral autograft, or autogenous chondrocyte implantation were excluded.

Thirty one subjects were excluded and 4 subjects refused operation. Among them who met the inclusion criteria, 15 subjects refused to participate in the study. Eighty subjects were recruited and informed consents for the surgery and study were obtained. Demographics of the subjects are presented in Table I. All the subjects were diagnosed by physical examination and MRI, and were confirmed by arthroscopy. Lachman test and pivot shift test were conducted under anesthesia before reconstruction. The subjects were grouped by computer generated randomization : 40 in group I and 40 in group II. The ACL was reconstructed using free tendon Achilles allograft fixed with Endobutton CL (Smith & Nephew, Endover, MA, USA) in femoral tunnel and Bio-interference screw (Arthrex, Naples, FL, USA) in tibial tunnel, which was augmented on tibial cortex with direct cortical fixation using spiked washer screw (group I) or post-tie using washer screw (group II).

Surgical technique

Tibial tunnel was made at footprint or 7 mm anterior to posterior cruciate ligament with the angle of 45 degrees to the tibial shaft. Femoral tunnel was made at footprint via anteromedial portal with the knee flexion of 120 degrees or more. The size of the reamer for the tibial and femoral tunnels was 9 mm.

The fresh frozen Achilles tendon allograft was thawed at room temperature. Calcaneal bone block was removed with the attached tendon preserved. It was usually separated by manual tension without difficulty. The free tendon was folded into a two-strand graft and was trimmed to be 9-mm thick. The length of the two-strand graft was set to be 12-12.5 cm for group I and 9.5-9.8 cm for group II. The graft was looped over the Endobutton CL with the appropriate length and 20 mm of looped end of the graft was whipstitched with No.1 Vicryl (Ethicon, Somerville, NJ, USA). Three centimeters of each of the two free ends was whipstitched with No.2 Ethibond (Ethicon, Somerville, NJ, USA) and each of two strings on each free end of the graft was retained. The looped end was marked at the position where it was to be seated in the femoral socket to ensure that the graft became completely seated in the femoral socket by arthroscopy. Twenty to twenty-five millimeters of looped end of the graft was inserted into femoral tunnel via tibial tunnel. Before tibial fixation, 20 times of full range of knee motion cycles under maximal manual load were conducted for pretensioning.

Tibial tunnel was fixed with 7*23 mm or 8*23 mm Bio-interference screw. After drilling at 1-2 cm distal to the anterior aperture of tibial tunnel, in group I, the free ends of the graft were fixed with spiked washer under manual tension. In group II, each two slinging sutures on the ends of the strands were tied together around the washer screw.

Postoperative rehabilitation

Quadriceps strengthening exercise was performed immediately after the surgery, partial weight bearing was allowed on the third day and full weight bearing was allowed as tolerated. Continuous passive motion (CPM) exercise was begun on the second postoperative day, and it was allowed up to 90 degrees of flexion until the fourteenth day, 120 degrees until the sixth week, and full range of motion afterward. After 12 weeks, jogging and stationary bicycling were allowed. After 6 months, subjects were allowed to do competitive sports except for those exercises that might involve strong contacts with others such as football or soccer, or those exercises that might impose strong external forces on the subjects' knee such as skiing or snowboarding. All kinds of exercises were allowed after 9 months.

Assessment of outcomes

Lachman test and pivot shift test were graded according to the IKDC 2000 criteria and were evaluated by two

orthopaedic surgeons that are independent to the surgery preoperatively and at the last follow-up. IKDC classification and Lysholm score were evaluated preoperatively and at the last follow-up. Range of motion of the reconstructed knee was compared to that of uninjured knee at the last follow-up. Tegner activity scale was evaluated before injury and at the last follow-up. Stress radiographs were taken while each knee was in flexion of 30 degrees and was loaded 150N using Telos stress device (Austin & Associate Inc., Fallston, MD, USA) preoperatively and at the last follow-up. Side-to-side difference (SSD) was measured by two orthopaedic surgeons using picture archiving and communication system (GE Healthcare, Chicago, IL, USA). Single-leg hop test (SLH) was performed at the last follow-up, in which the maximal distance out of three trials was adopted and analyzed as percentage of that of uninjured leg.

Statistical analysis

The statistical analyses of differences in continuous variables between two groups were performed with student t test and differences in categorical variables with Mann-Whitney U test, chi-square test, and Wilcoxon signed rank test. Interobserver and intraobserver reliability was assessed by intraclass correlation coefficient (ICC) with the respective 95% confidence intervals. SPSS version 17.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. The minimum level of significance was 0.05.

Table I. — Demographics

| Variables | Group I (n = 40) | Group II (n = 40) | <i>P</i> |
|--|--|-----------------------------|--------------------|
| Type of supplementary fixation | Direct cortical fixation using spiked washer screw | Post-tie using washer screw | |
| Mean age (years) (\pm SD ^a) | 28.3 \pm 9.2 | 27.2 \pm 9.6 | 0.594 ^b |
| Male:female | 34:6 | 35:5 | 0.745 ^c |
| Laterality (right:left) | 18:22 | 16:24 | 0.654 ^c |
| Mean BMI (kg/m ²) (\pm SD ^a) | 23.3 \pm 2.6 | 23.6 \pm 2.1 | 0.522 ^b |
| Mean period from injury to operation (weeks) (\pm SD ^a) | 8.5 \pm 9.4 | 6.5 \pm 7.8 | 0.315 ^b |
| Mechanism of injury | | | 0.664 ^c |
| Sports | 31 | 29 | |
| Fall down | 4 | 6 | |
| Traffic accident | 4 | 5 | |
| Unknown | 1 | 0 | |

^aStandard deviation.

^bStudent t test.

^cChi square test.

Table II. — Lachman test, pivot shift test, and IKDC classification at the last follow-up

| | Group I (n = 36) | Group II (n = 35) | <i>P</i> |
|---------------------|------------------|-------------------|--------------------|
| Lachman test | | | 0.072 ^a |
| negative | 23 (63.9%) | 29 (82.9%) | |
| 1+ | 6 (16.7%) | 5 (14.3%) | |
| 2+ | 7 (19.4%) | 1 (2.9%) | |
| 3+ | 0 (0%) | 0 (0%) | |
| Pivot shift test | | | 0.413 ^a |
| negative | 25 (72.2%) | 29 (82.9%) | |
| 1+ | 7 (19.4%) | 4 (11.4%) | |
| 2+ | 4 (11.1%) | 2 (5.7%) | |
| 3+ | 0 (0%) | 0 (0%) | |
| IKDC classification | | | 0.150 ^a |
| A | 20 (55.6%) | 26 (74.3%) | |
| B | 9 (25.0%) | 7 (20.0%) | |
| C | 7 (19.4%) | 2 (5.7%) | |
| D | 0 (0%) | 0 (0%) | |

^aChi square test.

RESULTS

Thirty six in group I and 35 in group II followed up for at least 2 years. Eight subjects were lost to follow up and one subject had re-injury to the same knee during soccer and was excluded. Interobserver ICCs for Lachman test, pivot shift test and SSD were over 0.8 and intraobserver ICC for SSD was 0.940. Preoperative Lachman test was grade 2 or 3 in all subjects. At the last follow-up, seven (19.4%) in group I and one (2.9%) in group II showed grade 2 or 3 on Lachman test ($p = 0.027$). Four (11.1%) in group I and two (5.7%) in group II showed grade 2 or 3 on pivot shift test at the last follow-up. ($p = 0.414$) All subjects showed C or D in IKDC classification preoperatively. Twenty nine (80.6%) in group I and thirty three (94.3%) in group II showed A or B in IKDC classification at the last follow-up ($p = 0.082$) (Table II). Mean Lysholm score was 59.5 ± 8.1 preoperatively and 92.2 ± 4.6 at the last follow-up ($p < 0.001$) (Table III). One subject in group I and two subjects in group II showed limitation of motion compared to the other knee ($p = 0.539$) and all of those were 5 degrees or less. Median Tegner activity scale was 7 (range,

5-9) before injury and 6 (range, 4-9) at the last follow-up ($p = 0.001$) (Table IV). Mean SSD was 9.8 ± 4.0 mm preoperatively and 2.1 ± 2.2 mm at the last follow-up ($p < 0.001$) (Table V). The average value on SLH was $88.5 \pm 5.7\%$ in group I and $90.4 \pm 5.0\%$ in group II compared to the other knee at the last follow-up ($p = 0.127$). Twenty seven subjects (75.0%) in group I and six (17.1%) in group II complained of irritation of soft tissue or tenderness on the bump at the site of supplementary fixation during follow-up ($p < 0.001$). All of their fixatives were removed at least one year after surgery and the complaints did not last any longer. Any other complications were not observed during the follow-up period in either group.

DISCUSSION

The results of this study showed statistically significant differences in Lachman test (negative or 1+ vs. 2+ or 3+) and SSD between two groups although the other clinical outcomes of both groups were not significantly different. Fixation methods in ACL reconstruction are largely divided into three categories including compression (eg. metal or

Table III. — Mean Lysholm score

| | Preoperative | | | Last follow-up | | |
|---|----------------|----------------|--------------------|----------------|----------------|--------------------|
| | Group I | Group II | <i>P</i> | Group I | Group II | <i>P</i> |
| Lysholm score (\pm SD ^a) | 59.8 \pm 7.8 | 59.2 \pm 8.4 | 0.755 ^b | 91.7 \pm 5.5 | 92.7 \pm 3.5 | 0.372 ^b |

^aStandard deviation.

^bStudent t test.

Table IV. — Median Tegner activity scale

| | Pre-injury | | | Last follow-up | | |
|-------------------------------|------------|----------|--------------------|----------------|----------|--------------------|
| | Group I | Group II | <i>P</i> | Group I | Group II | <i>P</i> |
| Tegner activity scale (range) | 7 (5-9) | 7 (5-9) | 0.289 ^a | 6 (4-8) | 6 (4-9) | 0.369 ^b |

^aMann-Whitney U test.

^bWilcoxon signed rank test.

Table V. — Mean SSD on Telos stress device

| | Preoperative | | | Last follow-up | | |
|------------------------------------|---------------|---------------|--------------------|----------------|---------------|--------------------|
| | Group I | Group II | <i>P</i> | Group I | Group II | <i>P</i> |
| SSD (mm) (\pm SD ^a) | 9.7 \pm 4.0 | 9.9 \pm 3.9 | 0.613 ^b | 2.4 \pm 2.4 | 1.4 \pm 1.6 | 0.048 ^b |

^aStandard deviation.

^bStudent t test.

biodegradable interference screw), expansion (eg. Rigidfix), and suspension (eg. Endobutton, Endopearl, Transfix, or Bone mulch). The results of soft tissue-to-bone fixation with metal or biodegradable interference screw has been demonstrated as not very promising in many studies (1,10,17). Although its fixation strength in outside-in technique may be somewhat better, fixation strength in tibial tunnel is less than that in femoral tunnel, and it may not be enough to bear stress regarding that normal daily load in the intact ACL is approximately 450N (19,20). Magen *et al* (16) reported that the failure load of interference screw, which was 350N, was not enough in tibia. Wang *et al* (27) reported that the graft slipped about 7 mm under 400 N load in the study of the fixation strength of the biodegradable interference screw in tibial tunnel. Weimann *et al* (29) reported that the graft slippage was 4.1 mm after 1000 cyclic load of 250 N. In addition to interference screw fixation in tibial tunnel, augmentation with staple or spiked washer is often conducted due to its less stable fixation (13,30,26). Nagarkatti *et al* (21) showed that augmenting soft tissue fixation

on tibial tunnel with an anchor of polylactic acid ball or cortical bone disk significantly increased the stiffness of the construct. Weiler *et al* (28) showed that supplementation of interference screw fixation of soft tissue graft with an Endopearl device increased pullout strength from 385.9 \pm 185.6 N to 658 \pm 118.1 N and increased stiffness from 25.69 \pm 8.47 N/mm to 41 \pm 11 N/mm. However, direct cortical fixation of the graft with spiked washer screw has a high profile, so bump under the skin may be a major dissatisfaction for the subjects. Furthermore, the authors have often experienced screw loosening during tightening the spiked washer screw to firmly fix the graft. Sometimes, cutting off a suture by spike or sharp margin of the spiked washer also happens. Graft slippage often cannot be prevented even though supplementary fixation to the tibial end using spiked washer and the outcomes may be disappointing due to considerable residual laxity (8). There have been few studies comparing fixation strength between direct cortical fixation with spiked washer screw and post-tie with washer screw. This study showed that post-tie with tethering sutures at

each free end of looped graft contributed satisfactory outcomes in terms of residual laxity compared to direct fixation of the graft to the tibial cortex with spiked washer screw. Lee *et al* (15) reported that supplementary fixation with staple or push-lock screw did not increase the structural strength and stiffness of the soft tissue graft fixation with biodegradable interference screw in porcine knee. However, this may not be applied to clinical situation and fixation strength of interference screw is greater in porcine knee as it is denser than human knee. Moreover, bone mineral density in the proximal tibia decreases after ACL injury (3,4). Bailey *et al* (2) reported that the properties of interference screw fixation for soft tissue graft in porcine tibia were overestimated compared with young human tibia. Hill *et al* (10) reported that supplementary staple fixation on tibia was effective to reduce anterior displacement of the tibia. Six weeks of performing the activities of daily living corresponds to approximately 220,000 cycles to the ACL at a tensile load of 169 N (19). Tensile strength of No. 2 ethibond, which is about 120 ~ 130 N (11), is relatively less than the stress to the ACL in daily living activity. Miller *et al* (18) reported that the failure loads of orthocord, fiberwire and manbraid were superior to that of the ethibond in a mechanical study for suture material. It may be more secure if these materials are used instead of ethibond. However, the number of sutures at the end of each strand is totally four and the post-tie is supplementary to first line fixation using interference screw, therefore the authors do not think this would be an issue.

Five to ten millimeters of the tibial end of the graft was left out of tunnel to prevent suture cut by sharp margin of the tibial tunnel entrance. Further studies are needed to clarify whether this method is helpful in preventing rupture of suture material. A screw with no thread about 5mm next to the head of screw was used and post-tie was performed after insertion of the threaded portion of the screw into the bone to prevent suture cut by thread of the screw.

Based on the results of this study, the null hypothesis has been accepted, and there are also benefits to conduct post-tie using washer screw rather than direct cortical fixation using spiked

washer screw in terms of profile and costs while expecting good outcomes.

This study has a few limitations. First, the follow-up period was short. Second, the author did not distinguish between the femoral side and the tibial side as a cause of the residual laxity. The graft was fixed with Endobutton CL in the femoral side to minimize the slippage, however a further study would be needed to identify whether the residual laxity during follow-up is due to slippage on tibial side or not. Third, there was no control group to show that a supplementation would be a better option for tibial fixation. Controversy may still exist whether a supplementation is necessary in addition to interference screw. However, Noh *et al* (22) previously reported that the supplementary tibial fixation was helpful in restoration of the stability. At least, post-tie would be a better option than direct cortical fixation using spiked washer screw if supplementation would have been applied.

CONCLUSIONS

Post-tie using washer screw as a supplementary tibial fixation in ACL reconstruction was more effective than direct cortical fixation using spiked washer screw to restore stability. Post-tie using washer screw may be recommended regarding relatively lower profile at the fixation site.

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