Comparison Between Early and Late Retensioning of an Adjustable-Loop Cortical Suspension Device During Hamstring ACL Reconstruction

Nam-Hong Choi,* MD, Bong-Seok Yang,†‡ MD, Hang-Ki Kang,* MD, Kyu-Wan Kim,† MD, Han-Bit Kim,† MD, and Brian N. Victoroff,§ MD

Investigation performed at the Eulji Medical Center, Seoul, Republic of Korea

Background: Biomechanical studies have demonstrated significant loosening of the adjustable-loop device as compared with the fixed-loop device used in anterior cruciate ligament reconstruction. Retensioning of the adjustable loop has been recommended; however, the timing of the retensioning is unknown.

Hypothesis: Early (ER) and late retensioning (LR) will show similar gapping between the femoral tunnel and graft on follow-up magnetic resonance imaging (MRI) and similar clinical outcomes.

Study Design: Cohort study; Level of evidence, 3.

Methods: This study included 101 patients who underwent hamstring anterior cruciate ligament reconstruction using the adjustable-loop device for femoral fixation between June 2016 and January 2018. All patients a had follow-up MRI on postoperative day 1. Patients with revision surgery and those with reinjury after reconstruction were excluded. In the ER group, retensioning and knot tying of the initially tightened adjustable loop were performed after the flip of the button and before the graft was fixed at the tibia. In the LR group, retensioning and knot tying were performed after initial tightening of the adjustable loop and graft fixation at the tibial side. The tunnel-graft gap measured on multiplanar reformatted images of MRI scans was compared between the groups, as were clinical outcomes.

Results: The mean age of the patients at the time of surgery was 30.3 years (range, 14-61 years). ER and knot tying were performed in 56 patients and LR and knot tying in 45. Preoperative characteristics of the 2 groups showed no significant differences. The mean ± SD tunnel-graft gap was 1.5 ± 2.0 mm in the ER group and 5.4 ± 4.0 mm in the LR group ($P < .001$). There were no significant differences in clinical outcomes between the groups.

Conclusion: ER and knot tying demonstrated less tunnel-graft gap than that of LR. However, there were no differences in clinical outcomes according to the timing of retensioning.

Keywords: adjustable-loop device; anterior cruciate ligament; hamstring tendon graft; retensioning

The adjustable-loop cortical suspension device is a relatively new device for fixation of soft tissue grafts at the femoral side in anterior cruciate ligament (ACL) reconstructions. An important advantage of the adjustable-loop device (ALD) as compared with the fixed-loop device is an ability to pull the graft completely to the top of the femoral tunnel. Complete filling of the graft within the femoral tunnel can decrease the distance between the fixation device and the graft and potentially prevent the "bungee cord" effect. Another advantage is the ability to retension a loosened adjustable loop during ACL reconstruction.[6] Therefore, secure tightening of the adjustable loop is mandatory to maintain the fully inserted graft within the femoral tunnel. However, several biomechanical studies[5,11] demonstrated significant loosening of the ALD as compared with the fixed-loop device. A systemic review revealed that 11 of 13 biomechanical studies reported significantly larger maximum irreversible displacement in ALDs than fixed-loop devices.[10] The ALD also exhibited greater displacement at the preloading condition and most displacement during the first cycle when compared with the fixed-loop device.[2,11]

Retensioning is proposed by several researchers[8,9,11] to prevent significant displacement during cyclic loading. Petre et al[11] suggested retensioning of the adjustable loop after initial cycling of the knee and fixation of the graft.

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Monaco et al[8] reported that all-inside ACL reconstruction with preconditioning leads to significantly improved mechanical behavior and may allow for optimizing initial graft tension and elongation for all-inside ACL reconstruction to reduce knee laxity. Noonan et al[9] suggested that retensioning and knot tying after initial reduction of the hamstring tendon graft may reduce loop slippage and displacement with cyclic loading during postoperative rehabilitation. However, the biomechanical effect of the retensioning is still debated. Smith et al[12] indicated negative initial elongation with retensioning of ALDs. Johnson et al[7] stated that retensioning did not significantly alter the biomechanical properties of ALDs. The effect of retensioning of the adjustable loop in the knee of the patient is rarely investigated in the literature.[4] There is also a paucity of literature concerning the timing of the retensioning of the ALD during ACL reconstructions.[6] If a loosened adjustable loop can be retightened by retensioning, late retensioning (LR) can be performed after final fixation of the graft. If a loosened adjustable loop cannot be retensioned, early retensioning (ER) may be preferred.

Recent studies[3,4] have reported that reformatted images of 3-T magnetic resonance imaging (MRI) can demonstrate the gap between the top of the femoral tunnel and the graft. This tunnel-graft gap, measured at immediate follow-up MRI, may indicate loosening of the adjustable loop within the femoral tunnel. The purpose of this retrospective study was to compare the tunnel-graft gap on follow-up MRI and clinical outcomes between ER and LR. We hypothesized that ER and LR will show similar tunnel-graft gaps and clinical outcomes.

METHODS

Patients

Inclusion criteria were as follows: (1) hamstring ACL reconstructions using the adjustable-loop cortical suspension device (TightRope; Arthrex) for femoral fixation between June 2016 and January 2018, (2) MRI conducted on the immediate postoperative day, and (3) follow-up for a minimum of 2 years after surgery. Patients with revision surgery were excluded, as were patients whose medical charts had no description of the method of retensioning. Patients who were lost to 2-year follow-up or experienced reinjury after reconstruction were also excluded. Overall, 116 patients underwent hamstring ACL reconstruction using the ALD. Seven patients had revision surgery; 4 did not receive follow-up MRI; and 4 had no record of the type of retensioning. Therefore, 101 patients were enrolled in this study. This retrospective study protocol was reviewed and approved by an institutional review board, and all patients signed an informed consent form.

Surgical Procedures

The semitendinosus and gracilis tendons were harvested and prepared for a quadrupled graft. A circumferential mark was made 25 mm from the proximal end of the graft. The graft was placed on the tensioning board before insertion into the tibial and femoral tunnels. The tibial tunnel was prepared according to the measured diameter of the quadrupled graft. A guide pin was inserted to the center of the femoral footprint of the ACL, and a femoral tunnel 25 mm long was created using a modified transtibial technique. The guide pin was advanced out of the skin of the distal thigh, and a small skin incision was made along the guide pin. The passing and tensioning sutures were passed through the tibial and femoral tunnels using the guide pin. The button of the ALD was passed through the femoral tunnel and flipped on the lateral cortex of the distal femur by distal traction applied to the graft. The tensioning sutures were pulled slowly and robustly to insert the graft completely into the femoral tunnel. Arthroscopic visualization confirmed that the mark on the graft was flush with the outlet of the femoral tunnel.

In the ER group, retensioning was performed, and a reverse half-hitch knot was made to prevent loosening of the adjustable loop. After that, the graft was cyclically loaded, and the Intrafix tibial sheath and screw (DePuy Mitek) were used for tibial fixation with the knee flexed at 20°. In the LR group, retensioning was performed, and a reverse half-hitch knot was made after graft fixation at the tibia. In the ER and LR groups, maximal force at retensioning was applied to 2 strands of the adjustable loop. ER and knot tying were performed during the early period of this study, and LR was performed in later periods. Therefore, the type of retensioning was not allocated randomly between the groups.

Tight contact of the button of the ALD on the lateral cortex of the distal femur was confirmed in all patients on immediate postoperative radiographs. Follow-up images using 3-T MRI (Magnetom Verio; Siemens Healthcare) were obtained from all patients on the immediate postoperative day before weightbearing to evaluate the position of the hamstring tendon graft within the femoral tunnel. Using 3-T MRI, 2-dimensional conventional sequences consisted of the following: axial proton density (PD) transverse high bandwidth, sagittal T2 turbo inversion recovery

‡Address correspondence to Bong-Seok Yang, MD, Department of Orthopaedic Surgery, Gwangmyeong Sungae Hospital, 36, Digital-ro, Gwangmyeong, 14241, Republic of Korea (email: faridat80@gmail.com).

*Department of Orthopaedic Surgery, Eulji Medical Center, Seoul, Republic of Korea.

†Department of Orthopaedic Surgery, Gwangmyeong Sungae Hospital, Gwangmyeong, Republic of Korea.

§Department of Orthopaedic Surgery, Case Western Reserve University, Cleveland, Ohio, USA.

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Ethical approval for this study was obtained from the Eulji Medical Center (EMCIRB 19-73).

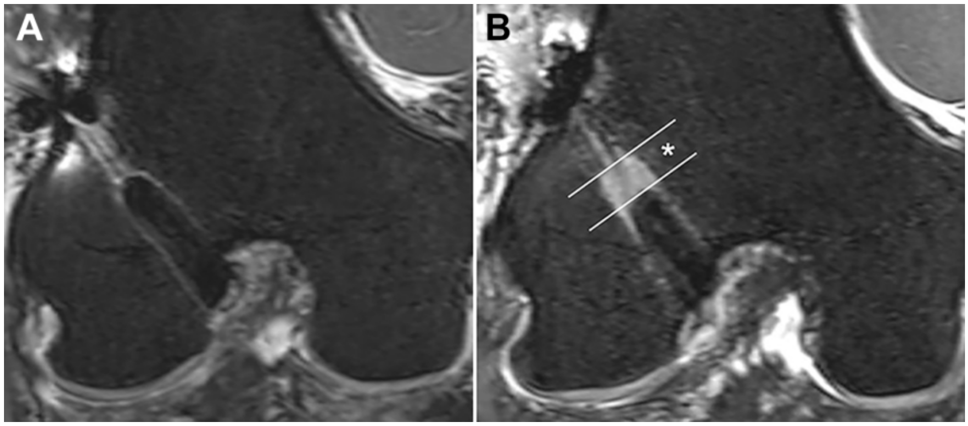

Figure 1. Reformatted 3-T magnetic resonance images show (A) a completely inserted hamstring tendon graft within the femoral tunnel in the early-retensioning group and (B) an incompletely inserted hamstring tendon graft within the femoral tunnel in the late-retensioning group. The asterisk indicates the tunnel-graft gap.

magnitude, sagittal turbo spin echo, and coronal T2 and PD. Additionally, a 3-dimensional PD sampling perfection with application-optimized contrasts using different flip angle evolutions (SPACE; Siemens Healthcare) was acquired in the sagittal plane. To view the entire length of the femoral tunnel, 3-dimensional PD SPACE sequences were subsequently reformatted into oblique coronal images by a magnetic resonance technologist using a console with commercially available software (Syngo MR; Siemens Healthcare). The reformation was performed with 0.5-mm slice thickness. During review of reformatted images, an oblique coronal image was chosen showing a 25-mm length of the femoral tunnel. The distance between the top of the femoral tunnel and the top of the hamstring tendon graft (tunnel-graft gap) was measured by an orthopaedic fellow who was blinded to the method of retensioning (Figure 1). All measurements were performed on a PACS (Picture Archiving and Communications System; General Electric).

Postoperatively, an identical postoperative rehabilitation protocol was recommended for both groups. Partial weightbearing using a brace was allowed after follow-up MRI evaluation. Closed kinetic chain exercises were started as early as possible. Full weightbearing was permitted 6 weeks after surgery. Jogging was started after 8 weeks and return to sports activity was allowed after 10 months.

Postoperative Evaluation

At 2 years after surgery, postoperative knee laxity was evaluated with the Lachman test, pivot-shift test, and KT-1000 arthrometer measurement (MEDmetric Corp). KT-1000 arthrometer testing was performed at maximal manual forces. An experienced orthopaedic technician who was blinded to the type of the retensioning performed KT-1000 arthrometer measurements. Functional evaluations were performed using the Lysholm score and Tegner activity scale. Knee laxity and functional scores were evaluated by an orthopaedic fellow who was blinded to the type of retensioning.

TABLE 1
Preoperative Characteristic Data of the Study Groups[a]

	ER Group (n = 56)	LR Group (n = 45)	*P*
Age, y	29.3 ± 12.4	31.3 ± 11.7	.416
Sex, male/female	47/9	37/8	.513
Follow-up period, mo	26.3 ± 3.0	25.1 ± 1.1	.089
Meniscal repair/meniscectomy	25/9	18/4	.385

[a]Data are reported as mean ± SD or No. of patients. ER, early retensioning; LR, late retensioning

Statistical Analysis

In a pilot study of 10 patients from each group, the mean and standard deviation of the tunnel-graft gap were calculated. For an alpha value of 0.05, the power was 0.87. Therefore, the numbers of patients in the 2 groups had sufficient power for statistical analysis. Lysholm score, Tegner activity scale, and tunnel-graft gap were compared between the groups using a Mann-Whitney test. Lachman and pivot-shift tests and patients with tunnel-graft gap $\leq$3 mm were compared between the groups using a chi-square test. Analysis was performed using SPSS for Windows (Version 12.0; IBM), and significance was assumed at $P < .05$.

RESULTS

The mean age of the patients at the time of surgery was 30.3 years (range, 14-61 years); there were 84 male and 17 female patients. ER and knot tying were performed in 56 patients and LR and knot tying in 45. Preoperative characteristics of the 2 groups are described in Table 1.

TABLE 2
Comparison of Postoperative Radiologic Outcomes[a]

	ER Group (n = 56)	LR Group (n = 45)	P
Tunnel-graft gap, mm	1.5 ± 2.0	5.4 ± 4.0	**<.001**
Tunnel-graft gap			**<.001**
≤3 mm	48 (85.7)	14 (31.1)	
≥4 mm	8 (14.3)	31 (68.9)	

[a]Data are reported as mean ± SD or n (%). Bold *P* values indicate statistically significant difference between groups ($P < .05$). ER, early retensioning; LR, late retensioning.

TABLE 3
Comparison of Postoperative Clinical Outcomes[a]

	ER Group (n = 56)	LR Group (n = 45)	P
Test, grade 0/1/2			
Lachman	45/11/0	30/15/0	.094
Pivot shift	42/8/6	30/12/3	.294
KT-1000 measurement, mm	1.5 ± 1.8	2.2 ± 1.6	.058
Postoperative			
Lysholm score	92.6 ± 7.3	92.8 ± 6.3	.894
Tegner activity scale	5.2 ± 1.4	5.5 ± 1.5	.495

[a]Data are reported as mean ± SD or No. of patients. ER, early retensioning; LR, late retensioning.

Characteristics, follow-up period, and meniscal surgery between the groups did not differ.

The mean ± SD tunnel-graft gap was 1.5 ± 2.0 mm in the ER group and 5.4 ± 4.0 mm in the LR group ($P < .001$) (Table 2). In the ER group, 48 patients had a tunnel-graft gap ≤3 mm and 8 had a gap ≥4 mm, while in the LR group, 14 patients had a tunnel-graft gap ≤3 mm and 31 had a gap ≥4 mm. There was a significant difference between the groups ($P < .001$). There were 24 patients in the ER group and 9 patients in the LR group with no tunnel-graft gap.

Table 3 shows the results of the postoperative knee laxity and functional outcomes of both groups. There were no statistically significant differences between the groups on any postoperative outcome measure. The mean KT-1000 measurement of laxity was smaller in the ER group versus the LR group; however, this difference was not statistically significant ($P = .058$).

DISCUSSION

The most important finding of this study was that ER and knot tying demonstrated less tunnel-graft gap than that of LR. ER may be helpful to prevent loosening of the adjustable loop that is secured by initial tensioning. However, the timing of retensioning showed no differences in the clinical outcomes.

The exact reason why there is a gap between the top of the femoral tunnel and the hamstring tendon graft is unknown. First, the hamstring tendon graft may not be fully inserted by tightening the adjustable loop during surgery. The marking line on the graft was flush with the aperture of the femoral tunnel in every patient. That meant complete insertion of the graft. However, the marking line could be blurred during passage of the graft and would be inaccurate. Second, the tightened adjustable loop may be loosened during surgery. After initial tightening of the adjustable loop at the femoral side, cyclic loading of the graft using flexion and extension of 15 to 20 times was performed for pretensioning of the graft. This pretensioning procedure may loosen the adjustable loop.[3] Biomechanical studies have shown that the ALD exhibited greater displacement at the preloading condition and is most susceptible to displacement during the first cycle.[5,11] Also, pulling of the graft distally during fixation of the graft at tibia may loosen the tightened adjustable loop.

It is not clear that the gap between the top of the femoral tunnel and the graft means loosening of the secured loop after initial tightening. However, loosening of the adjustable loop was demonstrated by several biomechanical studies.[1,5,11] Recent studies[3,4] using 3-T MRI showed that the hamstring tendon graft was not fully inserted in some patients. Increased tunnel-graft gap also correlated negatively with the Lysholm score.[4] Therefore, the tunnel-graft gap is clinically meaningful, and a method to prevent loosening of the adjustable loop needs to be considered.

Some researchers recommended retensioning of the adjustable loop.[11] Several biomechanical studies investigated the effect of retensioning in the ALDs. Johnson et al[7] reported that retensioning did not significantly alter the biomechanical properties of ALDs. However, Noonan et al[9] demonstrated that retensioning and knot tying reduced final elongation in the ALD by 88% when tested under relatively unloaded conditions (ie, cyclic loading of 10-250 N). In a tendon-bone-implant model, retensioning and knot tying reduced final ALD elongation by 45%. Monaco et al[8] indicated that intraoperative preconditioning increases initial graft tension for single- and both-side knotted configurations as compared with controls. Dynamic elongation is reduced for one- and both-side knotted configurations by 61% and 47%, respectively. Different methods of retensioning in the aforementioned 2 studies might be a cause of contradictory results. Johnson et al[7]retensioned ALDs after preconditioning and before cyclic loading. Noonan et al[9] retensioned them after an initial cycling. Biomechanical studies[5,11] have shown that the ALD exhibits most displacement during the first cycle. A repetitive graft loading-unloading situation may create an unfavorable loading condition for an ALD, resulting in loop lengthening after ACL reconstructions.[12]

The timing of the retensioning after initial tightening is not determined. After a flip of the button of the device, cyclic loading and graft fixation at the tibia are necessary while pulling the graft. These 2 steps may induce loosening of the adjustable loop. Clinical reports after retensioning of the ALD are very rare. Gamboa et al[6] reported a retensioning technique of the adjustable loop during ACL reconstruction. They retensioned the ACL graft by alternating both strands of the tensioning suture after tibial fixation of the graft and cyclic loading because they believed that the loop can be retensioned to remove that dynamic elongation. They confirmed that the graft was taut and fully inserted into the femoral tunnel by arthroscopy. However, they did not confirm complete insertion of the graft into the femoral tunnel using follow-up MRI. In this present study, 32 of 56 patients in the ER group and 36 of 45 in the LR group showed various gaps between the femoral tunnel and the graft. The ER group showed less tunnel-graft gap than the LR group, and 85.7% of the patients had a tunnel-graft gap $\leq$3 mm.

Clinical effects of retensioning of the ALD in hamstring ACL reconstruction have been rarely reported. A recent study demonstrated that the mean tunnel-graft gap increased from 2.1 ± 2.8 mm on the immediate postoperative day to 4.6 ± 3.5 mm at 6 months after surgery although ER was performed. Loss of tension applied to the graft by femoral and tibial fixation and loosening of the tightened adjustable loop by early flexion and weightbearing during the postoperative period were suggested as reasons for increased tunnel-graft gap.[4] Therefore, conservative rehabilitation needs to be considered after hamstring ACL reconstructions using an ALD, although retensioning is performed. Barrow et al[1] suggested that the more important clinical concern regarding the mechanical properties of ALDs may be the volume of cycles rather than the intensity of load experienced postoperatively.

There were several limitations in this study. First, this study was a retrospective one. Selection bias could affect the radiological and clinical outcomes. However, strict inclusion and exclusion criteria were applied in this study. Second, the numbers of the patients of both groups were relatively small. However, power analysis showed that the number of patients in each group was enough. Third, different forces applied for the device to be retensioned would affect the tunnel-graft gap. Although there is no defined force for retensioning, Smith et al[12] applied 200 N for retensioning. In this study, maximal force for retensioning was applied to 2 strands of the adjustable loop.

CONCLUSION

ER showed less tunnel-graft gap when compared with LR. However, there was no difference in clinical outcomes according to the timing of retensioning.

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