Clinical and radiographic results after ACL reconstruction using an adjustable-loop device

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Abstract

Background: The femoral cortical suspension device such as fixed loop devices (FLDs) and adjustable-loop device (ALD) are used for ACLR technique in recent days. However, there was few studies of clinical and radiographic results for ACLR using ALD. This study was conducted to clarify the clinical and radiographic results, stability and bone tunnel enlargement after ACLR using a ToggleLoc with a zip loop as ALD.

Methods: 80 patients who had data available from the most recent follow-up at ≥2 years since ACLR were evaluated both clinical and radiographic results. They were divided into single bundle reconstruction group (SBR) and double bundle reconstruction group (DBR). Clinical scores were included subjective scores and objective scores at pre- and postoperatively 2 years. The subjective scores were the Cincinnati knee rating system, Knee injury and Osteoarthritis Outcome Score (KOOS), Lysholm score, Tegner activity score, Visual Analog Scale (VAS) and ACL-Return to Sport after Injury (RSI) scale. The objective scores were the isokinetic muscle strength, side-to-side difference in anterior instability and single hop test. In radiographical assessment, femoral and tibial tunnel enlargement was evaluated by three-dimensional computed tomography.

Results: In both SBR and DBR group, the postoperative subjective scores were significantly improved compared to the preoperative values, except for the Tegner activity score. Similarly, the side-to-side differences in muscle strength, anterior instability and single hop test were significantly improved after surgery. The changes in the femoral and tibial tunnel maximum cross section areas of SBR were 104.3 ± 21.2 % and 89.2 ± 15.2 %, respectively, at 2 years post-operatively. In DBR, in the femoral bone volume change of the antero medial (AM) and postero lateral (PL) bundle were 107.0 ± 3.5 % and 108.1 ± 3.3, and in the tibial bone volume change of AM and PL bundle were 90.6 ± 3.3 % and 87.0 ± 4.2 %. At the femoral site, the rate of tunnel enlargement increased for the first 12 months and then decreased through 24 months postoperatively. At the tibial site, by contrast, the rate of tunnel enlargement decreased consistently over the two-year postoperative follow-up.

Conclusion: This is the first study to include clinical data on ACLR using a ToggleLoc with a zip loop device. ACLR using these devices as ALDs resulted in good clinical outcomes and provided good stability of the knee with relatively little bone tunnel enlargement in both SBR and DBR group.

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1. Introduction

A number of fixation devices have been developed, including femoral cortical suspension devices, cross-pins and bioabsorbable interference screws. In recent years, fixed loop devices (FLDs) and adjustable-loop devices (ALDs) have gained traction for anterior cruciate ligament reconstruction (ACLR), as they are simple to use and provide excellent results. FLDs, such as the Endobutton CL (Smith & Nephew, Andover, MA, USA) can be fixed easily at the distal femoral cortex, and the femoral tunnel can be completely filled with a hamstring graft without any implant. The Endobutton
CL shows desirable biomechanical properties when fixing the hamstring graft. The ultimate failure loads when tested as a construct were higher for the Endobutton CL (1456 N) than for the ToggleLoc with ZipLoop (1334 N; Zimmer-Biomet, Warsaw, IN, USA). Cyclic displacements after 1000 cycles in a porcine construct were significantly shorter for the Endobutton than for the ToggleLoc with ZipLoop (1.88 mm vs. 3.34 mm). Given its advantages, the Endobutton has become the most frequently used fixation device. However, many reports have found that the Endobutton is associated with greater bone tunnel enlargement than other devices. Although the causes of bone tunnel enlargement after ACLR are multifactorial, including biological and mechanical factors, distant suspensory fixation is strongly associated with greater bone tunnel enlargement.

Adjustable-loop cortical suspension devices, such as the ToggleLoc with ZipLoop, are relatively new fixation devices for ACLR using the hamstring graft and are similar to FLDs. One advantage of ALDs is the ability to draw the graft to the depth of the bone tunnel in order to achieve adequate graft tension while minimizing the empty space in the tunnel. Because the adjustable loop can reduce the distance between the button of the ToggleLoc with ZipLoop and the proximal end of the hamstring graft, this reduced distance of suspensory fixation may potentially decrease the “bungee cord effect”, resulting in less postoperative bone tunnel enlargement.

Indeed, histologic assessments have shown significantly better graft incorporation with healing to bone for grafts using ALDs in sockets than for grafts using interference screw fixation in tunnels.

However, few reports have described the clinical and radiographic results and bone tunnel enlargement after ACLR using ALDs. The outcomes of ACLR using ToggleLoc with ZipLoop in particular have not been evaluated at all. Therefore, in the present study, we evaluated the utility of ToggleLoc with ZipLoop as an ALD for ACLR, hypothesizing that this approach would result in good clinical outcomes and eliminate bone tunnel enlargement.

### 2. Materials and methods

This retrospective study was approved by our institution ethics committee (IRB No. 2019-11).

#### 2.1. Patients

A total of 242 patients with ACL injury underwent ACLR from July 2013 to 2018 in our institution. The exclusion criteria for this study were as follows: (1) ACLR using an autologous graft, such as bone-to-bone and gracilis with anything other than the semitendinosus tendon; and (2) ACLR using a device other than a ToggleLoc with ZipLoop. (3) We excluded 45 patients who underwent ACLR using bone-to-bone and 10 who underwent ACLR using a device other than ToggleLoc with ZipLoop device. Fifty-four patients did not have available data and there were not 3DCT data in 52 patients. We therefore ultimately assessed the clinical and radiographic results in the 80 patients who had data available from the most recent follow-up at ≥2 years since ACLR. They were divided into single bundle reconstruction group (SBR) and double bundle reconstruction group (DBR) (Fig. 1).

#### 2.2. Surgical procedure

Surgical technique of ACLR was based on original article which was reported by Kubota et al. It was performed by far anterior medial (FAM) portal technique, therefore femoral bone tunnel was drilled in deep knee flexion. Semitendinosus tendon was harvested and graft was prepared to two-strand double bundle, or four-strand single bundle. ToggleLoc with ZipLoop was used for femoral cortical suspension device, and Telos artificial ligament and staple (Ai-medic, Tokyo, Japan) were used for tibial fixation. A 15 mm femoral socket is created with a drill adjusted to the diameter of the graft under the arthroscopy. The appropriate diameter of the tibial tunnel is also created using the ACL tibial guide (Zimmer-Biomet). After sizing the femoral tunnel, we are marking 15–20 mm width in the loop of the ToggleLoc with ZipLoop at the same length as the femoral tunnel from the end of the button. While passing the graft, the tensioning sutures are placed in front of the loop to make them passing to the medial portal smoothly. Furthermore, the lateral side of the button faces lateral side in the arthroscopic view because it
makes the button to flip easier. The proximal femoral passing suture and distal tibial adjustable loop is pulled to the opposite direction with the hands of the surgeon during passing the button. We stop pulling the sutures just at the proximal marking area with feeling the button passed over the lateral femoral cortex. The distal graft end is held distally with moderate tension during passing the button. After the tensioning suture is pulled out to FAM portal, it is pulled to draw the ACL graft into the femoral tunnel. If the graft fits the femoral tunnel, it's confirmed that the graft can't be displaced distally. Finally, the distal artificial ligament was fixed by double staple while tensioning distally for 50 N at 20° knee flexion (Fig. 2).

2.3. The clinical evaluation score at follow-up

The subjective scores—namely the Cincinnati knee rating system, Knee injury and Osteoarthritis Outcome Score (KOOS), Lysholm score, Tegner activity scale and Visual Analog Scale (VAS)—were evaluated for all patients preoperatively and at 2 years postoperatively. The objective scores—namely the isokinetic muscle strength, side-to-side difference (SSD) in anterior instability using KS measure (Nippon Sigmax Co., Ltd., Tokyo, Japan) and SSD of isokinetic muscle strength of quadriceps and hamstrings using Easy tech plus (Inter Reha, Inc, Tokyo, Japan) —were assessed at the same time as the clinical examination. The ACL-Return to Sports after Injury (RSI) scale was evaluated for all patients at six months and two years after ACLR.

2.4. Bone tunnel enlargement calculation

Bone tunnel enlargement was assessed using three-dimensional computed tomography (3DCT). All patients underwent 3DCT within two weeks after surgery and again at one and two years after surgery using a helical high-speed SOMATOM Definition Edge (Siemens AG, Munich, Germany) or Aquilion ONE (Toshiba Medical Systems, Tochigi, Japan) CT machine. The AZE VirtualPlace software package (AZE, Tokyo, Japan) was used for 3D reconstruction of the operated knee. To assess the femoral tunnel aperture, the patella and medial femoral condyle were removed from the 3D model because it was necessary to visualize the lateral wall of the intercondylar notch (Fig. 3A and B). To assess the tibial tunnel aperture,

Table 1
Patients' characteristics.

|                          | All (n = 80) | SBR (n = 66) | DBR (n = 14) | p value |
|--------------------------|-------------|-------------|-------------|---------|
| Age (years)              | 30.7 ± 12.9 | 32.3 ± 12.3 | 24.2 ± 9.2  | 0.06    |
| BMI                      | 23.7 ± 3.5  | 23.8 ± 3.8  | 23.1 ± 3.1  | 0.38    |
| Sex                      |             |             |             |         |
| Female                   | 44          | 40          | 4           | 0.07    |
| Male                     | 36          | 26          | 10          |         |
| Side                     |             |             |             |         |
| Right                    | 36          | 30          | 6           | 0.85    |
| Left                     | 44          | 36          | 8           |         |
| Concomitant injury       | None 44     | None 37     | None 7      | 0.68    |
| MM tear                  | 15          | 14          | 1           |         |
| LM tear                  | 19          | 13          | 6           |         |
| MM tear - LM tear        | 2           |             |             |         |

Data are shown as the means with standard deviation or number.
SBR: Single bundle reconstruction, DBR: Double bundle reconstruction, BMI: body mass, MM: medial meniscus, LM: lateral meniscus.

Fig. 3. Measurement method of maximal cross-section areas in bone tunnel by 3-D CT scans. (A) The maximal cross-sectional areas of the femoral tunnel in post-operative, (B) the maximal cross-sectional areas of the femoral tunnel in post-operative 1 year, (C) the maximal cross-sectional areas of the tibial tunnel in post-operative, and (D) the maximal cross-sectional areas of the tibial tunnel in post-operative 1 year.
SBR: Single bundle reconstruction, DBR: Double bundle reconstruction, KOOS: Knee injury and Osteoarthritis Outcome Score, VAS: Visual analog scale, Quad: quadriceps, Ham: hamstring.

The bone tunnel cross-section areas (two weeks, one year and two years postoperatively) were compared using an analysis of variance (ANOVA) with repeated measures. To compare pre- and postoperative clinical subjective and objective scores, we used a paired t-test. A value of p < 0.05 was considered to be statistically significant. The Mann-whitney test and the chi-square test was used in demographic data.

3. Results

3.1. Patients’ characteristics

The characteristics of the patients are described in Table 1. There were 36 males and 44 females, with a mean age of 30.7 ± 12.9 years old. The mean BMI was 23.7 ± 3.5 kg/m². The injured side was the right knee in 36 and left knee in 44. Concomitant injury was medial meniscus (MM) injury in 15, lateral meniscus (LM) injury in 19 and both MM and LM injury in 2. (Table 1). The patients were divided into SBR group and DBR group. There were 26 males and 40 females, with a mean age of 23.8 ± 3.8 years old in SBR group, and 10 males and 4 females, with a mean age of 23.1 ± 3.1 years old in DBR group. The mean BMI was 23.8 ± 3.8 kg/m² in SBR group and 23.1 ± 3.1 kg/m² in DBR group. The injured side was the right knee in 36 and left knee in 44 with SBR group, and in 6 and in 8 with DBR group. Concomitant injury was MM injury in 14, LM injury in 13 and both MM injury and LM injury in 2 with SBR group, and in 1 and in 6 with DBR group. There were no significant differences between two groups (Table 1).

Table 2
The comparison of the clinical results between pre- and post-operative 2 year.

|                               | Pre              | Post-2 year          | p     |
|-------------------------------|------------------|----------------------|-------|
|                               | SBR              | DBR                  | FR    |
| Cincinnati Knee Rating System | 248.7 ± 58.3     | 384.6 ± 50.2         | <0.001** |
| Symptom                       | 72.9 ± 15.9      | 91.6 ± 10.6          | <0.001** |
| Pain                          | 74.9 ± 17.6      | 93.7 ± 9.7           | <0.001** |
| ADL                           | 84.4 ± 14.0      | 97.6 ± 4.7           | <0.001** |
| Sports                        | 42.0 ± 27.4      | 86.9 ± 17.2          | <0.001** |
| QOL                           | 39.5 ± 18.4      | 81.9 ± 17.4          | <0.001** |
| Lysholm Score                 | 75.1 ± 16.4      | 95.4 ± 8.3           | <0.001** |
| Tegener activity score        | 6.1 ± 0.9        | 6.2 ± 1.1            | 0.11  |
| VAS                           | 22.8 ± 21.4      | 4.6 ± 6.9            | <0.001** |
| Sports                        | 75.6 ± 25.9      | 17.4 ± 22.5          | <0.001** |
|                               |                  |                      |       |
|                               | Post-6 months    | Post-2 year          | p     |
|                               | SBR              | DBR                  | FR    |
| SBR vs DBR at post-2 year     |                  |                      |       |

SBR: Single bundle reconstruction, DBR: Double bundle reconstruction, KOOS: Knee injury and Osteoarthritis Outcome Score, VAS: Visual analog scale, Quad: quadriceps, Ham: hamstring, SSD: side to side difference.

Table 3
Maximal cross-section areas and volume change in femoral and tibial tunnel.

|                               | Post-operative (mm²) | Post-1 year (mm²) | Post-2 year (mm²) | Tunnel change (%) |
|-------------------------------|----------------------|-------------------|-------------------|-------------------|
|                               | SBR                  | DBR               | SBR vs DBR at post-2 year |
| Femoral tunnel (mm²)          | 64.3 ± 18.2          | 69.9 ± 19.3       | 67.1 ± 19.7       | 104.3 ± 21.2      |
| Tibial tunnel (mm²)           | 64.9 ± 19.4          | 63.7 ± 17.7       | 57.9 ± 16.9       | 89.2 ± 15.2       |

|                               | Post-operative (mm³) | Post-1 year (mm³) | Post-2 year (mm³) | Tunnel change (%) |
|-------------------------------|----------------------|-------------------|-------------------|-------------------|
|                               | SBR                  | DBR               | SBR vs DBR at post-2 year |
| Femoral tunnel (mm³)          | 34.1 ± 4.3           | 37.4 ± 3.9        | 36.5 ± 4.5        | 107.0 ± 3.5       |
| Tibial tunnel (mm³)           | 31.4 ± 2.6           | 34.7 ± 3.4        | 33.8 ± 4.8        | 108.1 ± 3.3       |

SBR: Single bundle reconstruction, DBR: Double bundle reconstruction.

the patella and femoral condyle were removed (Fig. 3C and D). A true medial view of the femur was established by superimposing the posterior aspects of the femoral condyles. All measurements were made on the surface of the lateral wall of the intercondylar notch completely from an orthogonal projection to the angle of the surface being measured to ensure accuracy. A true supra-inferior view of the tibial condyle was established to visualize the articular surface of tibial plateau. Two radiological technicians (KM and Jolla, CA, USA). Changes in the bone tunnel cross-section areas were presented in percentages as the mean with the standard deviation (SD). The bone tunnel cross-section areas (two weeks, one year and two years postoperatively) were compared using an analysis of variance (ANOVA) with repeated measures. To compare pre- and postoperative clinical subjective and objective scores, we used a paired t-test. A value of p < 0.05 was considered to be statistically significant. The Mann-whitney test and the chi-square test was used in demographic data.

2.5. Statistical analyses

The statistical analyses were performed using the GraphPad Prism® biostatistics software program (Graph Pad software inc, La Jolla, CA, USA). Changes in the bone tunnel cross-section areas are presented in percentages as the mean with the standard deviation (SD). The bone tunnel cross-section areas (two weeks, one year and two years postoperatively) were compared using an analysis of variance (ANOVA) with repeated measures. To compare pre- and postoperative clinical subjective and objective scores, we used a paired t-test. A value of p < 0.05 was considered to be statistically significant. The Mann-whitney test and the chi-square test was used in demographic data.

3. Results

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3.2. Clinical evaluations

All subjective and objective scores are summarized in Table 2. Subjective scores, including the Cincinnati knee rating system, KOOS, Lysholm score and VAS score, were significantly improved at two years after surgery compared to the preoperative values, except for the Tegner activity score, which was not markedly different at two years after surgery compared with before surgery. Similarly, the objective scores, including the SSD of the anterior translation of the knee using a KS measure and the SSD of the isokinetic muscle strength of the atrophied quadriceps and hamstrings using an Easytect plus, were significantly improved at two years after surgery compared to the preoperative values. There were no significant differences between two groups at two years after surgery (Table 2).

3.3. 3DCT analyses of bone tunnel cross section areas

The changes in the femoral and tibial tunnel maximum cross section areas in SBR were 104.3 % ± 21.2 % and 89.2 % ± 15.2 %, respectively, at 2 years post-operatively. In DBR, the femoral bone volume change of the anteromedial (AM) and posterolateral (PL) bundle were 107.0 % ± 3.5 % and 108.1 % ± 3.3, and in the tibial bone tunnel change of AM and PL bundle were 90.6 % ± 3.3 % and 87.0 % ± 4.2 % (Table 3). Furthermore, the femoral tunnel of both SBR and DBR was expanded over the first postoperative 12 months but shrank from 12 to 24 months (Fig. 4A–C), whereas the tibial tunnel of both SBR and DBR was remained closed throughout the first 24 months after surgery (Fig. 4D–F). There were no significant differences in the size of the tunnel expansion at each time point.

4. Discussion

The present study showed that ACLR in both SBR and DBR using a ToggleLoc with ZipLoop as an ALD resulted in significantly improved clinical outcomes at two years postoperatively compared with the preoperative values. In addition, the femoral and tibial tunnel enlargement was not significantly different from that noted in other studies and was reported about natural history of them. Adjustable loop femoral cortical suspension devices have recently begun to be used for ACLR. Several biomechanical studies have compared the outcomes of ACLR with FLDs and ALDs. Some authors have suggested that the effect of cyclic loading on the lengthening of adjustable-length devices, such as the Tight...
Tunnel and ToggleLoc with ZipLoop, is a potential area of clinical concern, as these devices may loosen after ACLR. However, no clinical evaluation has been conducted concerning ALDs. Boyle et al. found no significant difference in the postoperative knee stability or graft failure rate between an FLD (RetroButton; Arthrex Inc., Naples, FL, USA) and an ALD (TightRope RT; Arthrex Inc.) in patients receiving ACLR.26 In addition, our data showed that the clinical and radiographic results using ToggleLoc with ZipLoop as ALD were significantly improved at two years after surgery compared to preoperative values. These findings suggest that it may not be clinical problem as the biomechanical data to loosen graft after ACLR using ALD. Furthermore, to our knowledge, this is the first study to include clinical data on ACLR using a ToggleLoc with a zip loop device from two years postoperatively.

Various methods have been employed to measure the bone tunnel area after ACLR, including X-ray, 3DCT and magnetic resonance imaging. Some authors insist that 3DCT is the best method for evaluating the bone tunnel.15,20 Devices used for graft fixation in ACLR are known to contribute to bone tunnel enlargement,9 although a number of factors are involved in bone tunnel enlargement. These generally include mechanical factors (e.g. tunnel drilling technique, number of tunnels drilled, type of fixation device, bungee effect, wind shield wiper effect, redirecting forces at the tunnel entrance and thermographic effect) and biomechanical factors (e.g. proinflammatory factors, such as TNF-α, IL-1β, IL-6, IL-8, BMP and NO; osteolysis and synovial bathing effects).10,11 Previous studies have shown that differences in the fixation point between FLDs may exacerbate micromotion in the bone tunnel, resulting in increased bone tunnel enlargement.21,22 However, the bone tunnel enlargement experienced in ACLR using an ALD is controversial. Therefore, we used 3DCT to measure the cross-section areas of the bone tunnel after ACLR using a ToggleLoc with ZipLoop. The rate of femoral and tibial tunnel enlargement measuring by 3DCT in this study was smaller than that in other studies using 3DCT measurements.23–25 Mayr et al.23 reported that the rates of femoral tunnel enlargement at six months after hamstring single-bundle ACLR using a TightRope RT as an ALD vs. biodegradable interference screws (BioComposite; Arthrex Inc.) were 143.2% ± 34.4% vs. 119.8% ± 19.2 %. Araki et al.26 noted that the rate of femoral tunnel enlargement at 1 year after hamstring double-bundle (using the AM and PL bundle) ACLR using Endobutton CL (FLD) changed to 122.3% ± 31.8% and 112.5% ± 34.4%. Hwan et al.24 reported that the rates of femoral tunnel enlargement at 1 year after ACLR using hamstring grafts inserted in a press-fit technique (0.5-mm underdrilled tunnels) versus a conventional femoral technique (same-sized graft and tunnel) using transtibial pin fixation were 165% and 171.5%. Compared to these previous studies, our data suggested that the rate of femoral bone tunnel enlargement was small (Table 4). This may be because of a reduction in the bungee cord effect due to using an ALD. The FLD is required the creation of about 7–8 mm socket in addition to the length of the tendon graft in the bone tunnel creation. Therefore, bungee-effect and wind-shield wiper motion are likely to occur when the knee is flexed to compared with ALD. It may lead to bone tunnel enlargement and failure of union between the grafted tendon and bone tunnel. Since ALD can fixate the graft tendon in the bone tunnel more closely than FLD, it could be reduced the bungee-effect. Furthermore, our technique was a transportal technique conducted through the far-anteromedial (FAM) portal. A previous study suggested that drilling the femoral tunnel through the medial portal created a lower, more posterior and less vertical tunnel than the transtibial tunnel.26 Tunnel enlargement was greater with more anterior, more proximal and more vertical femoral tunnels created when drilling through the tibial tunnel was performed.26 Therefore, transportal technique may be effective more than transtibial technique to avoid tunnel enlargement.

In addition, there have been few reports on the natural history of bone enlargement. Weber et al. reported that the cross-section area decreased over two years postoperatively for the femoral tunnel midsection as well as both tibial and femoral tunnel exit sites.27 In both the tibial and femoral tunnels, the aperture and tibial midsection cross section areas generally increase in the first 24 weeks after surgery, eventually plateauing before decreasing in area from 1 year to the final follow-up at 2 years. In the present study, there were no significant differences in the rate of tunnel enlargement for the femoral and tibial tunnels over time (Fig. 4). Impressively, at the femoral site, the rate of tunnel enlargement increased for the first 12 months and then decreased through 24 months postoperatively. At the tibial site, by contrast, the rate of tunnel enlargement decreased consistently over the two-year postoperative follow-up. It would be taken time to union between the grafted tendon and bone tunnel to postoperative any month. Therefore, the tunnel enlargement may be caused for the first 12 months by micromotion etc. and then decreased. This study has limitations. First, we were unable to compare the bone tunnel enlargement experienced with an ALD with that experienced with an FLD in our institution, and the follow-up duration was relatively short.

In conclusion, to our knowledge, this is the first study to include clinical data on ACLR using a ToggleLoc with a zip loop device. ACLR in both SBR and DBR using these devices as ALDs resulted in good clinical outcomes and provided good stability of the knee with relatively little bone tunnel enlargement.

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Declaration of competing interest

The authors declare no conflicts of interest with this study.

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