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ARTHROSCOPY AND SPORTS MEDICINE

Does non-contact or delayed contact of an adjustable-loop femoral button affect knee stability following anterior cruciate ligament reconstruction?

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Abstract

Background The purpose of this study was to investigate whether cortical non-contact or delayed contact of an adjustable-loop button for femoral fixation could affect knee stability following anterior cruciate ligament (ACL) reconstruction.
Methods Eighty subjects who underwent single-bundle ACL reconstruction using an adjustable-loop femoral cortical button were retrospectively reviewed regarding patient demographics, graft size, combined surgery, and postoperative 2-year results of knee stability, functional scores, and radiographic tunnel widening. We compared the contact and the non-contact groups determined by position of the button observed in immediate postoperative radiographs. According to 2-year postoperative radiographs, the non-contact group was further divided into two subgroups (delayed contact and persisting non-contact subgroups) and results were compared.
Results The contact group had 46 patients and the non-contact group had 34 patients. The average gap distance in the non-contact group was 1.9 ± 0.6 (1.1–3.4) mm. There were no significant differences in KT-1000 arthrometric knee stability ($p = .667$) or Lysholm score ($p = .198$), or International Knee Documentation Committee (IKDC) score ($p = .091$) between the two groups. No significant differences in tunnel widening were found at femoral and tibial tunnels on anteroposterior and lateral radiographs ($p > .1$, all tunnels). In addition, delayed contact subgroup and persisting non-contact subgroup showed similar radiographic and clinical outcomes.
Conclusion Surgeons should strive to obtain cortical contact of the adjustable-loop femoral button. Nevertheless, cortical non-contact with less than 3 mm of gap distance did not affect knee stability, radiographic outcomes, or clinical outcomes.
Level of evidence Level III, retrospective comparative study.

Keywords ACL reconstruction · Adjustable-length loop · Contact or non-contact · Outcome

Introduction

Since the introduction of femoral suspensory device in anterior cruciate ligament (ACL) reconstruction, soft tissue interposition between femoral cortex and the femoral suspensory device has been one of the main concerns [1]. The extensor mechanism and the iliotibial band (ITB) can become interposed if the device is flipped too far from the femoral tunnel exit, resulting in friction or irritation with persistent pain [1–3]. In addition, early necrosis of the

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interposed tissue may weaken the fixation strength of the button [4]. Subsequent loss of graft tension and continuing graft-tunnel motion can negatively affect the healing process and consequently lead to reconstruction failure [5–8].

TightRope® (Arthrex, Naples, FL, USA) has an adjustable loop that fits all sizes of femoral tunnels, rendering it unnecessary to form an extra femoral socket (6–10 mm) to facilitate button flipping [9, 10]. However, the risk of soft tissue interposition is higher using a TightRope due to the lack of a side-trailing suture for flipping, and the longer loop compared to a fixed-length loop device [10, 11]. If the soft tissue is interposed, the button of the TightRope will not be observed to have contact with the femoral cortex on immediate postoperative radiographs. Therefore, it is important to identify implications of 'non-contact' of the button. Mae et al. [12] have reported that, after double-bundle ACL reconstruction, soft tissue interposition of the fixed-loop button does not have a correlation with the KT-1000 side-to-side difference or Lysholm score. Other studies have cautioned about detrimental outcomes that can result from femoral suspensory device-induced soft tissue interposition without suggesting any actual clinical outcomes [4, 10, 11, 13]. To the best of our knowledge, effect of cortical non-contact or delayed contact of an adjustable-loop femoral button following anatomic single-bundle ACL reconstruction has not been reported yet.

Therefore, the purpose of this study was to investigate whether cortical non-contact or delayed contact of an adjustable-loop femoral button in anatomic single-bundle ACL reconstruction could affect radiographic tunnel widening, knee stability, and functional outcomes at postoperative 2 years. Our hypothesis was that the cortical non-contact or delayed contact would not affect knee stability and clinical outcomes.

Materials and methods

Subjects

Inclusion criteria of this retrospective study were: (1) anatomic single-bundle ACL reconstruction with autogenous hamstring tendon using TightRope consecutively done by single senior surgeon between May 2013 and May 2016, and (2) patients who were followed up more than 2 years postoperatively. Among 87 ACL reconstructions who met the inclusion criteria, seven subjects were excluded (five surgeries of revision ACL reconstruction, and one surgery performed immediately following hardware removal of medial opening-wedge high tibial osteotomy, and one reconstruction that failed within 2 years postoperatively). Finally, 80 patients were enrolled in this study. This study was approved by the Institutional Review Board (IRB) of our hospital. All patients provided informed consent.

Surgical technique

All operations were performed using the anatomic single-bundle ACL reconstruction technique via an anteromedial (AM) portal. After confirming rupture of ACL, the ipsilateral gracilis and semitendinosus tendons were harvested and prepared as quadruple-strands. With the knee flexed at 120°, a femoral tunnel was drilled using a 7 mm offset ACL guide and a spade-tipped drill pin with an open eyelet (Arthrex, Naples, FL, USA) through the AM portal. After confirming the femoral condylar length, a femoral socket was formed to a 25 mm depth with a cannulated headed reamer sized according to the diameter of the prepared graft. Tibial tunnel was then prepared using a 45-degree tibial guide device with the same diameter as that of the femoral tunnel. Along the loading suture hooked in the open eyelet, the leading suture of the TightRope was passed through the femoral tunnel to the lateral aspect of the distal thigh. After retrieving the tensioning suture via the AM portal, the leading suture was pulled until just after the button passing the lateral femoral cortex. Cortical seating of the button was then confirmed by pulling the graft back and forth several times while grasping both leading and tibial end sutures. After tightly tensioning the graft, cyclic loading was applied 20 times while pulling the graft distally. The tibial side of the graft was fixed using a spiked-washer/cancellous screw and a bio-absorbable interference screw with knee in full extension. For subjects who underwent ACL reconstruction alone or ACL reconstruction with meniscectomy, full range of motion (ROM) exercise with partial weight bearing was permitted from the first day following surgery. Those with meniscal repair were limited to continuous passive motion (CPM) exercise and non-weight bearing until 6 weeks postoperatively. In both groups, full weight bearing was initiated at 6 weeks after the surgery.

Radiographic evaluation

'Cortical contact' was defined in cases where plain radiographs showed that the button had come into contact with the femoral cortex, on both ends or on the central area of the button, or when the gap between the button and the cortex was 1 mm or less (Fig. 1). 'Central' refers to the area between the two stitch holes on the button. In cases when the button was rotated and displaced anteriorly or posteriorly, only the central portion of the button touched the femoral cortex. Even when there was a radiolucent gap, the case was classified as being in the contact group if the gap was 1 mm

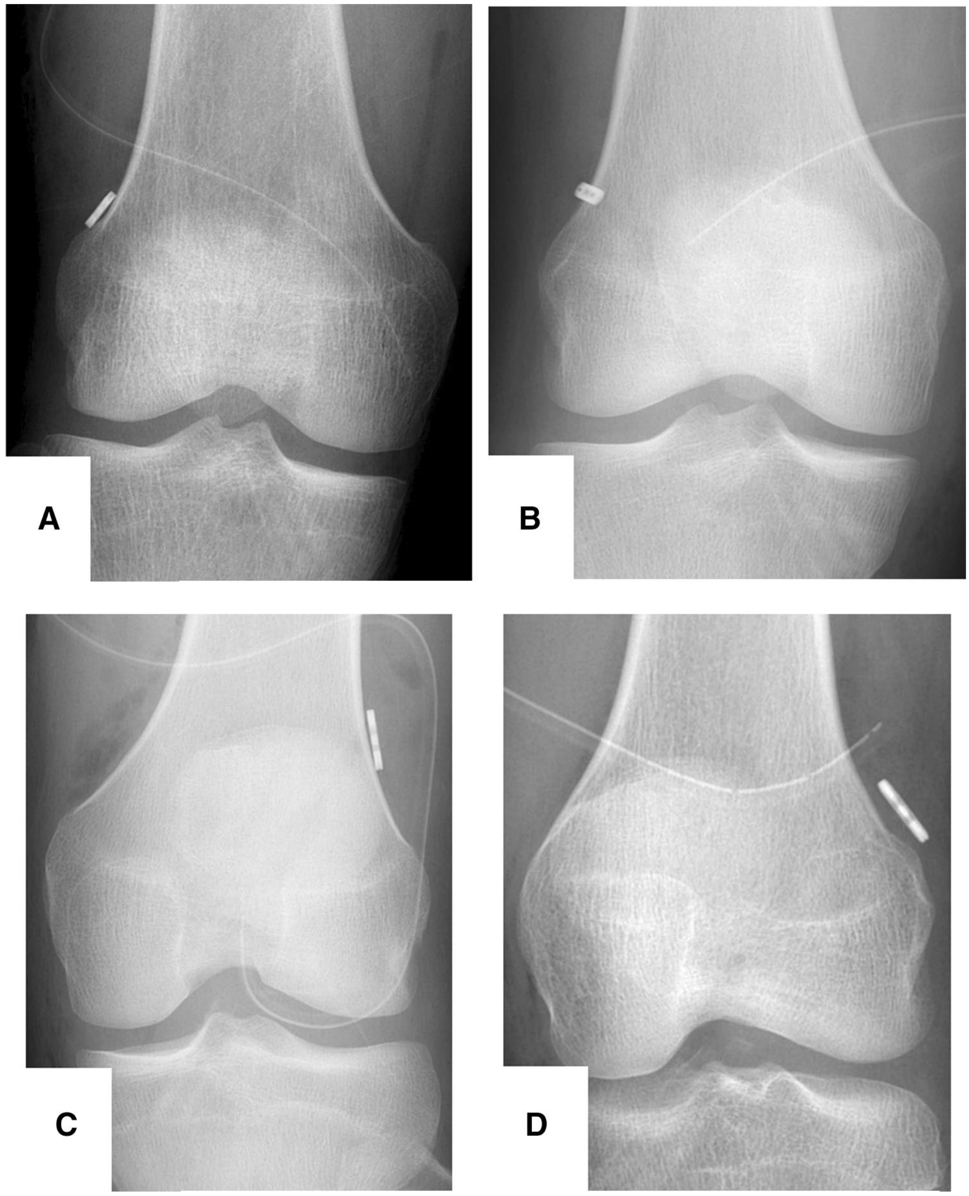

Fig. 1 Immediate postoperative plain radiographs. Three types of cortical contact (**a**–**c**). The button is in contact with the femoral cortex in **a** both ends, **b** central area, **c** a gap distance of 1 mm or less. **d** Cortical non-contact

or less at more than two-thirds the length of the button. This is a permissible range considering the thickness of the fibrous outer layer of the periosteum [12]. Cases of 'cortical non-contact' were confirmed when the gap exceeded 1 mm at more than two-thirds the length of the button.

Radiographs of the immediate post-operation and the latest follow-up were independently reviewed by orthopedic fellows, twice, with an interval of 4 weeks. κ statistics for the agreement of measurement showed substantial agreement of intra- and inter-observer testing for the contact or non-contact group (κ=0.78 and 0.79, respectively) [14]. Based on immediate postoperative knee anteroposterior (AP) and lateral radiographs, subjects were divided into two groups: cortical contact and non-contact groups. Based on postoperative 2-year radiographs, the non-contact group was further divided into two subgroups (delayed contact subgroup and persisting non-contact subgroup) according to whether or not the button moved to touch the femoral cortex during the follow-up period (Fig. 2). We also reviewed all postoperative radiographs of 6 weeks, 3, 6, 12 months, and yearly thereafter to determine the timing of the cortical contact and to confirm whether any button position had fluctuated. No fluctuation of the button position was observed in any subject during the serial follow-up. Once the button had shifted, it stayed shifted until the last follow-up. If it had not shifted, the initial status was maintained. Figure 3 shows a flow diagram of patient classification. The gap distance was measured as the shortest distance from the central portion on the cortical side of the button to the femoral cortex. Tunnel widths at proximal and distal one-third of femoral and tibial tunnels each were measured in both AP and lateral

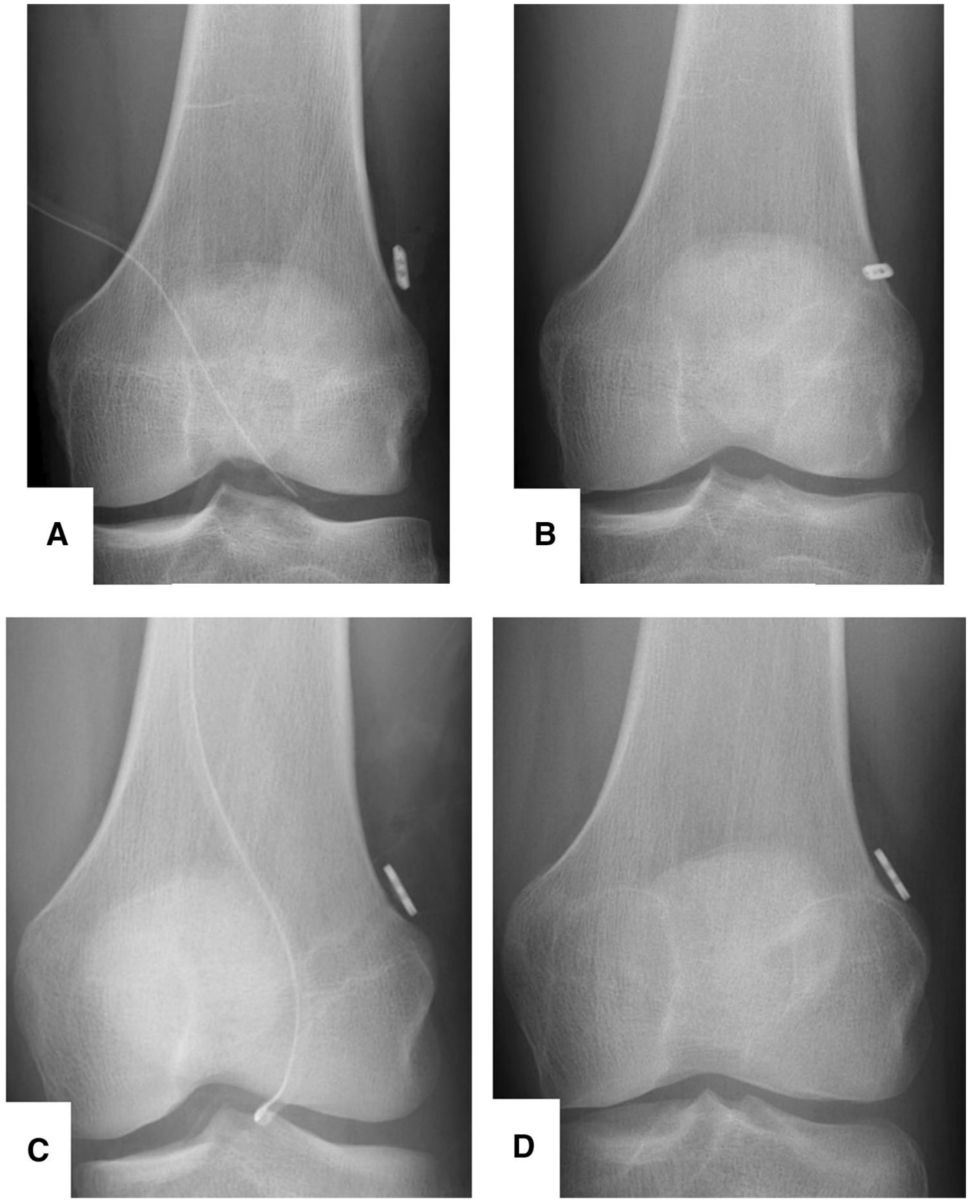

Fig. 2 Immediate and postoperative 2-year radiographs. **a**, **b** Postoperative 1-year radiograph showing delayed contact in an 18-year-old male patient. **c**, **d** Persistent non-contact in a 20-year-old male showing no interval change of the button's position

radiographs. The mean value of proximal and distal width at each tunnel was used to calculate the amount of tunnel widening between immediate and 2 years postoperatively (Fig. 4). The mean diameter was calculated from two measurements of each tunnel. The calculated mean diameter at postoperative 2 years was then compared with that of immediate postoperative radiographs.

Knee stability and functional outcome evaluation

Clinical outcomes were evaluated at postoperative 1 year and yearly thereafter by an orthopedic fellow who was blinded to whether or not the button had established cortical contact. Postoperative knee stability was evaluated using a KT-1000 arthrometer. Testing was performed repetitively to converge the mean laxity on each side of the knee. Functional outcomes were evaluated using Lysholm knee score [15] and the International Knee Documentation Committee (IKDC) score [16].

Statistical analysis

The sample size was calculated based on the hypothesis that the clinical outcomes would not differ between the two groups. The primary outcome was knee stability, as measured using a KT-1000 arthrometer. To reveal a 1 mm side-to-side difference, at least 32 subjects were needed in each group to achieve 80% power with an alpha of 0.05

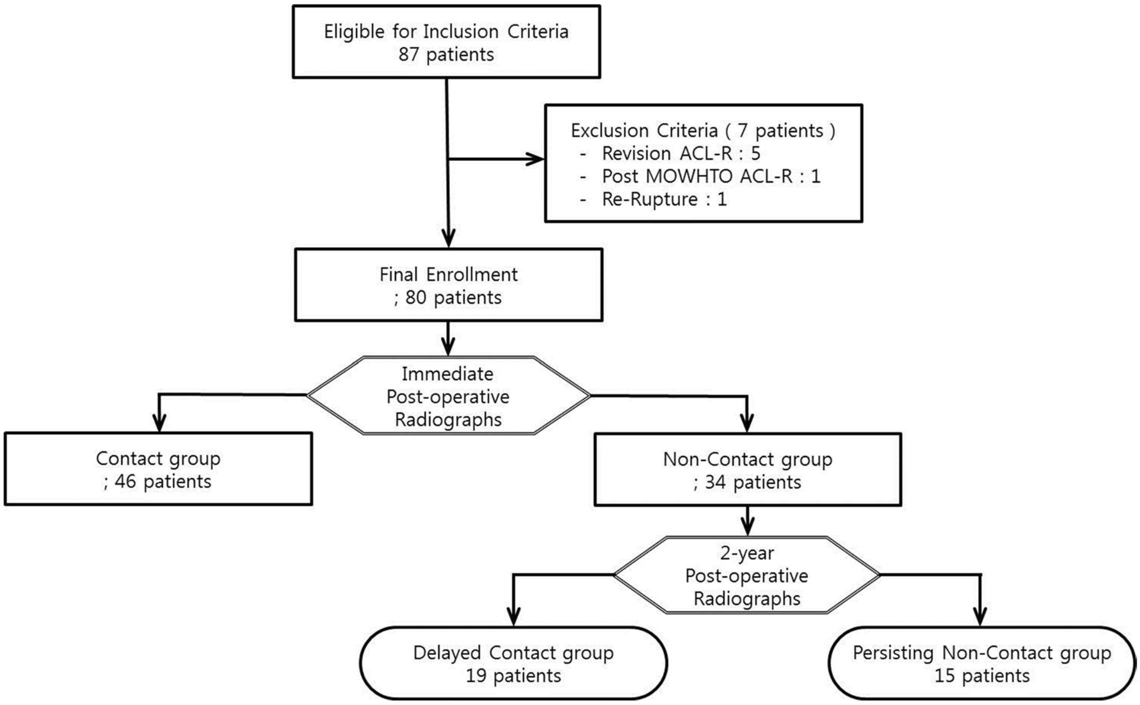

Fig. 3 Patient flow diagram. MOWHTO; medial opening-wedge high tibial osteotomy

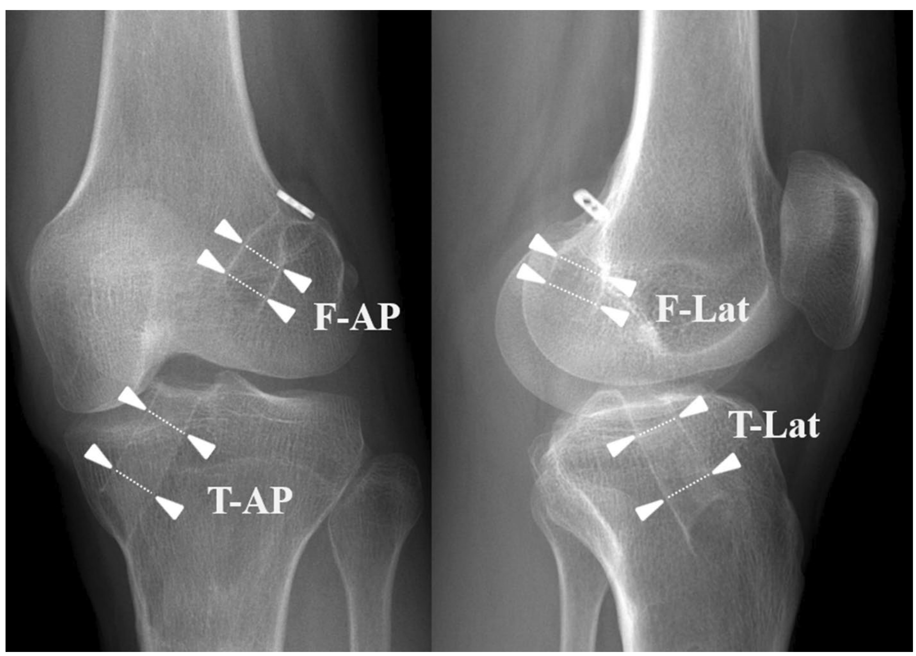

Fig. 4 Postoperative anteroposterior (AP) and lateral radiographs showing measurements of diameters of femoral and tibial tunnel at proximal and distal locations

and standard deviation of a prior study [17]. Independent *t* tests and Mann–Whitney *U* tests were used to analyze continuous variables such as tunnel widening, KT-1000 arthrometric side-to-side difference, and functional scores while Chi-squared tests and Fisher's exact tests were used to analyzed categorical variables. SPSS software program ver. 21.0 (SPSS Inc., Chicago, IL, USA) was used, for all statistical analyses. Statistical significance was considered at p value of $< .05$.

Results

Preoperative patient demographics, graft size, and incidence and treatment type of the meniscal injury were not significantly different between the contact group and non-contact group (Table 1). The average gap distance of the non-contact group as measured in immediate postoperative radiographs was 1.9 ± 0.6 mm (range from 1.1 to 3.4 mm). At 2 years postoperatively, amounts of femoral and tibial tunnel widening on AP and lateral radiographs were not significantly different between the contact and the non-contact groups (Table 2). Knee stability evaluated using side-to-side difference measured by a KT-1000 arthrometer and functional outcomes such as Lysholm and IKDC scores were also similar between the two groups at 2 years after the reconstruction (Table 2).

In subgroup analysis, the number of subjects was 19 (56% of the non-contact group) in the delayed contact subgroup and 15 (44%) in the persisting non-contact subgroups. Patient demographics such as graft size and incidence and treatment type of meniscal injury were similar between the two subgroups except age (29.6 ± 11.1 vs. 19.9 ± 6.6 years, delayed contact subgroup vs. persisting non-contact subgroup; $p = .003$). Average gap distances in immediate postoperative radiographs were 1.8 ± 0.5 mm (range 1.1 to 3.4 mm) in the delayed contact subgroup and 2.1 ± 0.6 mm (1.2 to 3.4 mm) in the persisting non-contact group ($p = .113$). After reviewing serial follow-up radiographs of the delayed contact group, the mean timing of delayed contact was 6.0 ± 5.4 months postoperatively. Seven cases had occurred within 3 months. Four cases had occurred between 3 and 6 months and eight had occurred after 6 months postoperatively. At 2 years after the surgery, the amount of tunnel widening on AP and lateral radiographs, side-to-side difference by KT-1000 arthrometer, and Lysholm and IKDC scores showed similar outcomes between the two subgroups (Table 3).

Discussion

The most important finding of this study is that the amount of tunnel widening, knee stability, and functional outcomes of the non-contact group were not inferior to those of the

Table 1 Demographics of the contact and non-contact groups

	Contact ($n = 46$)	Non-contact ($n = 34$)	p value
Age, years	29.8 ± 11.0 (15–55)	25.4 ± 10.4 (14–55)	.072
Gender, male (%)	35 (85)	25 (76)	.375
BMI, kg/m^2	24.1 ± 4.3 (19.0–42.9)	23.8 ± 4.7 (15.5–39.1)	.746
Side, left	19 (41)	19 (56)	.258
Graft size, mm	8.1 ± 0.7 (6–10)	7.9 ± 0.9 (6–9)	.490
Tourniquet time, m	63.9 ± 11.1 (48 -100)	66.0 ± 16.7 (45–95)	.545
Meniscal injury (%)	25 (58)	23 (70)	.344
Meniscectomy	13 (31)	6 (18)	.286
Meniscal repair	13 (42)	18 (55)	.059

Data are presented as mean ± standard error (min–max)

BMI, body mass index

Table 2 Radiographic tunnel widening, knee stability, and functional outcomes of the contact and non-contact groups

	Contact ($n = 46$)	Non-contact ($n = 34$)	p value
Tunnel widening, %			
Femur AP view	27.7 ± 20.9	31.9 ± 16.7	.345
Femur lateral view	30.7 ± 15.5	26.9 ± 14.8	.278
Tibia AP view	22.1 ± 17.6	22.5 ± 14.9	.904
Tibia lateral view	26.0 ± 15.3	24.5 ± 13.5	.649
KT-1000 (difference), mm	1.6 ± 0.9 (0–4)	1.5 ± 0.9 (0–4)	.667
Lysholm score	93.0 ± 8.4 (64–100)	95.2 ± 5.7 (75–100)	.198
IKDC score	81.1 ± 12.4 (52.9–100)	85.8 ± 11.6 (48.3–100)	.091

Data are presented as mean ± standard error (min–max)

IKDC, International Knee Documentation Committee

Table 3 Radiographic results, knee stability, and functional outcomes of the delayed contact and persisting non-contact subgroups

	Delayed contact ($n = 19$)	Persisting non-contact ($n = 15$)	p value
Immediate postoperative gap distance	1.8 ± 0.5 (1.1–3.4)	2.1 ± 0.6 (1.2–3.4)	.113
Tunnel widening, %			
Femur AP view	33.3 ± 18.2	30.1 ± 15.0	.586
Femur lateral view	26.2 ± 14.9	27.8 ± 15.2	.762
Tibia AP view	26.0 ± 17.0	18.2 ± 10.7	.132
Tibia lateral view	27.9 ± 13.7	20.1 ± 12.5	.098
KT-1000 (difference), mm	1.5 ± 0.9 (0–4)	1.5 ± 1.1 (0–4)	.937
Lysholm score	94.6 ± 6.5 (75–100)	95.9 ± 4.7 (85–100)	.542
IKDC score	84.2 ± 13.2 (48.3–98.9)	87.9 ± 9.3 (72.4–100)	.359

Data are presented as mean ± standard error (min–max)

BMI, body mass index; IKDC, International Knee Documentation Committee

cortical contact group at 2 years after the single-bundle ACL reconstruction using a TightRope for femoral graft fixation.

Graft-tunnel motion is one of the important factors for tunnel widening following ACL reconstruction [18]. As hamstring autografts have higher rate of tunnel widening than bone-patella-bone-tendon autografts, many studies have investigated optimal surgical options to reduce graft-tunnel motion [19–21]. When using Endobutton, tunnel widening explained by the "bungee cord effect" can be worsened by longitudinal graft motion due to additional tunnel drilling that is inevitably required to flip the button [18, 22]. In that aspect, TightRope has a definite advantage because the space between the proximal end of the femoral socket and the top of the graft is eliminated by the tightening of the loop. However, non-contact of the button followed by necrosis of the interposed tissue or delayed contact in early postoperative period may create as much space as the gap between the button and femoral cortex. This might cause the bungee cord effect. On the other hand, Choi et al. [22] have reported no significant differences between Endobutton with 15-mm length loop and 30-mm loop regarding tunnel widening and clinical outcomes. There was no significant difference in postoperative tunnel widening following ACL reconstruction between fixed-loop and adjustable-loop femoral suspensory button either [23]. Therefore, gaps of up to 3.4 mm observed in the non-contact group might have less negative impact given the difference of required femoral socket length between these two kinds of loop. Based on results of the present study with considering measurement errors, it appears that less than 3 mm of gap distance may be tolerable following autogenous single-bundle ACL reconstruction.

Although several studies have reported clinical relevance of the femoral suspensory button, evidence drawn from clinical outcomes is not yet sufficient regarding a detrimental effect of soft tissue impingement [1–3, 24]. Mae et al. [12] have reported no significant differences in limitation of motion, knee stability, or functional score between those with and without soft tissue impingement based on postoperative 1-year radiographs after 101 double-bundle ACL reconstructions using EndoButton (fixed-loop). Among 202 buttons, cortical non-contact was found 16 in AM grafts and 35 in posterolateral (PL) grafts. Results of present study showed similar functional outcomes between contact and non-contact groups. However, our study had higher reliability in the following aspects. First, we performed single-bundle reconstructions. Given that the AM bundle plays a more important role than the PL bundle [25–27], the high prevalence of tissue impingement on the PL graft reported in the previous study might cast doubt on the significance of their result. A detrimental effect of the soft tissue interposition would be revealed more sensitively in single-bundle reconstruction because there are no supplementary structures, as there are in the double-bundle techniques. Second, our study secured a minimum of 2 years of follow-up period.

Subgroup analysis has the highest clinical importance for evaluating the risk of soft tissue impingement. As we applied a stricter definition than the previous study [12], 'Delayed contact' implied that the soft tissue between the button and femoral cortex had degenerated or shrunk. Thus, the fixation power would have been weakened. Although the optimal graft tension during healing process was not determined, loosening of fixation might be related to graft–tunnel motion and fit or graft length within bone tunnel [5]. Equivalent positive outcomes between the two subgroups might be explained by the timing of the button's delayed contact. Considering that the critical period for tendon-to-bone healing is 8–12 weeks after reconstruction [28], two-thirds of delayed contact that happened after 3 months postoperatively appeared to contribute to the comparable results between the two subgroups.

Limitations of this study are as follows. First, this was a retrospective comparative study. However, all subjects were followed up on a regular basis according to our protocols for ACL reconstruction. As follow-up radiographs were taken at postoperative 2 and 6 weeks as well as 3, 6, and 12 months, precise detection of the timing of delayed contact was limited. Second, although secured by power analysis, the sample size was relatively small in this study. We believe that additional comparison with larger numbers of each group, especially of delayed contact and persisting non-contact subgroups, would provide deeper insight with reduced type II error risk. Third, to evaluate button position, we used plain radiography only in which the position could be read incorrectly depending on the rotation or tilting of the knee. However, computed-tomography (CT) images are inherently more vulnerable to artifacts than plain radiographs and metallic artifact is a well-known patient-based artifact [29]. In addition, repetitive CT testing for study purposes was impermissible in terms of research ethics due to unnecessary radiation hazard to the patients. To reduce measurement error, two orthopedic fellows judged the cortical contact independently, showing good intra- and inter-observer reliability. Despite the above-mentioned limitations, this is the first study comparing radiographic tunnel widening, knee stability, and clinical outcomes of the cortical contact and non-contact in anatomic single-bundle ACL reconstruction using a TightRope.

Conclusion

Cortical non-contact of the adjustable-loop button did not affect knee stability, radiographic outcomes, or clinical outcomes at a minimum follow-up of 2 years after surgery. Delayed contact patients were estimated to exhibit similar outcomes to persisting non-contact patients. Surgeons should strive to obtain cortical contact of the adjustable-loop femoral button. Nevertheless, cortical non-contact with small gap distance (< 3 mm) may be tolerable following single-bundle autogenous hamstring ACL reconstruction.

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Compliance with ethical standards

Conflict of interest All authors of this study declare that there is no conflict of interest relevant to this study.

Ethical approval This article does not contain any prospective studies with human participants or animals performed by any of the authors. IRB approval by IRB of Seoul St. Mary's Hospital, the Catholic University of Korea Study No.: KC17RESI0742.

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