

Short Term Clinical Outcomes of Fixed Length Loop Devices and Adjustable Length Loop Devices for Femoral Fixation of Hamstring Graft for Arthroscopic Anterior Cruciate Ligament Reconstruction: A Non-Randomized Comparative Trial

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Abstract

Background: In anterior cruciate ligament (ACL) reconstruction, cortical suspension devices are used widely. The two most commonly used cortical suspension devices for ACL reconstruction are fixed-length loop devices (FLDs) and adjustable length loop devices ALDs.

Aim: This study is aimed to compare the clinical outcomes between ALDs and FLDs in the femoral fixation component of ACL reconstruction using a hamstring graft.

Methods: It was a non-randomized trial that was conducted at tertiary care teaching hospital. The total sample size of the study was calculated as 34, in which 17 patients were placed in FLDs and the rest of 17 patients were placed in ALDs. Functional outcomes were measured by Lysholm score preoperatively and then postoperatively at one month, two months, and six months. Knee laxity was assessed by the Lachman test and Pivot shift test preoperatively and postoperatively at 6 months.

Results: The mean Lysholm score increased from 51.53±6.39 to 97.94±1.95 in FLD group and from 50.24±12.36 to 98.29±1.86 in ALD group at 6-month follow-up. No significant difference was found between the groups for Lysholm score at preoperatively and postoperative follow-ups ($p>0.05$). Lachman and Pivot shift test also showed no significant difference between the groups ($p>0.05$).

Conclusion: The short term clinical outcome of ACL reconstruction using FLD and ALD for femoral fixation of hamstring graft are similar.

Keywords: Anterior cruciate ligament reconstruction, Fixed length loop devices, Adjustable length loop devices, Lysholm score, Lachman test, Pivot shift test.

Introduction

Anterior cruciate ligament (ACL) injuries affects more than 200,000 people each year and for these injuries, ACL reconstruction is one of the common procedures for orthopaedic surgeries performed to restore the stability of the knee [1–4]. There are a variety of fixation devices available for the femoral fixation, it includes interference screw, transfix screw, and cortical suspension devices [5]. The devices must be ensured to facilitate healing and also to make the function of the knee to a normal state. The devices that can be used for the tibial fixation depends on the location of fixation which includes intra-tunnel fixation and extra-tunnel fixation. Intra-tunnel fixation methods rely on the metallic or the bioresorbable interference screw [6, 7]. Cortical suspension devices are commonly utilized for ACL reconstruction. There are mainly of two devices namely fixed fixed-length loop devices (FLDs) e.g., Endobutton (EB) and adjustable length loop devices (ALDs) e.g., Tightrope (TR). Advantages of FLDs include high biomechanical strength and good graft fixation in terms of limiting graft slippage and thus providing adequate graft strength; its

disadvantages includes that it requires an additional 6 mm of over drilling of the femoral socket to flip the button [8]. Another type of devices, ALDs are meant to allow the graft to adapt to varied tunnel lengths without leaving any extra space inside the tunnel. It may be tightened intra-operatively, which prevents over-drilling and improves bone preservation without leaving extra space in the bone tunnel [9, 10]. When compared to FLDs, the drawback with ALDs are that it does not provide enough biomechanical strength, resulting in loop lengthening and eventual graft slippage [8]. Under such circumstances, ALDs may interfere with the process of graft healing and also with the integration of graft that can eventually lead to knee instability and clinical failure of the graft.

Majority The majority of studies available are biomechanical studies, there are very few studies comparing the clinical outcomes of FLDs and ALDs. Therefore, our objective was to compare the clinical outcomes of FLDs and ALDs for femoral fixation of hamstring graft in arthroscopic ACL reconstruction by Lysholm score, Pivot shift test, and Lachman test throughout six months.

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Hypothesis

There would be no significant difference between clinical outcomes of FLDs and ALDs for femoral fixation of hamstring graft for arthroscopic ACL reconstruction.

Methods

Study Design

It was a non-randomized comparative trial in which subjects were placed into a 1:1 ratio. The study was conducted at the department of orthopaedics in a tertiary care teaching hospital. The study was approved by the institutional ethics committee. Written informed consent forms were obtained from the enrolled patients prior to randomization and was conducted in accordance with the Declaration of Helsinki principle. Enrolment of the patients were based on inclusion and exclusion criteria.

Patient Population

Sample The sample size was estimated by the formula, $n = 4 (SD)^2 / L^2$ where the mean value of Lysholm score was 85.7 ± 17.3 ; allowable error (L) = 10% of the mean from the literature [11]. The total sample size was calculated to be 34 patients which were divided into 17 patients in each study group i.e., FLDs and ALDs. Convenient A convenient sampling technique was used in the study. Patients in the age group of 18- 50 years with complete ACL tear on clinical exam and MRI, with or without meniscus tear but without any degenerative changes were included in the study. Patients with a bilateral ACL injury, previous knee surgery, previous fracture, previous knee infection, multiple ligament injuries were excluded from the study.

All enrolled patients had undergone arthroscopic ACL reconstruction surgery by the same surgeon. Preoperative clinical data was entered in data sheet. The patient functional outcomes were recorded by using the Lysholm score preoperatively and then postoperatively at one, two, and six months. The stability of the knee was assessed by the Pivot shift test and Lachman test at preoperatively and at six months by an Orthopaedic surgeon who was blinded to the type of procedure performed.

Data collection

Clinical outcome data was collected from patients and then entered the data in a Microsoft excel Excel spreadsheet. Follow Follow-up and data collection was done.

- Preoperatively
- Postoperatively at one, two, and six months.

Surgical Technique

Arthroscopy ACL reconstruction was done with FLDs or ALDs. Both the operative procedures were done under spinal/epidural anaesthesia whichever was suitable. Patient The patient was taken in the supine

position in the operation theatre. Prior to final positioning, the injured knee was examined under anaesthesia. The stability of joint, patella, and knee range of motion were assessed. After the examination of the affected knee under anaesthesia, a padded non-sterile tourniquet was placed high on the thigh on the operative limb. The patient was positioned in such a way that the operative leg was hanging off the end of the operating table on a leg holder, with the contralateral leg on a leg holder. The operative leg was prepped and draped in a standard fashion.

Approach and Assembly

A small stab incision was made with the knee in 90° flexion and standard anteromedial and anterolateral portals. The arthroscope sheath and the sharp trocar were then introduced into the knee joint.

Preparation of Hamstring Graft

Through an oblique incision, medial and distal to tibial tuberosity semitendinosus and gracilis tendons were harvested. The ends of the graft were secured with the help of the Ehibond suture. The tendon was folded on itself to make a four to five stranded graft. One end of the Semitendinosus graft was sutured to ALD loop/ FLD loop with No 2 high strength suture and the graft is folded on to itself to make 3 strand graft and then gracilis is folded to make it 5 strand graft. Then tensioning of the graft was done followed by sizing of graft. The size of the graft was always more than 8 mm. On the proximal end of the prepared graft, the OnButton CL FLDs or Buttonfix fixation (Biotek, Chetan Meditech Private Limited, Ahmedabad, India) fixation button with ALDs cortical fixation device was attached.

Graft Passage and Fixation

The prepared graft was passed through the tibial tunnel and the proximal end of the graft with cortical suspension device was pulled out through the femoral tunnel. The graft was pulled until cortical suspension devices (fixed and adjustable loop) flip outside the lateral femoral condyle. The distal end of the graft was fixed with help of an appropriate size tibia interface screw. In the case of ALDs, the trailing end of threads were pulled out after tibial fixation to tighten the graft and adjust the loop length. Wound The wound was closed after achieving haemostasis and compression dressing applied. Suture removal was done at on the post-operative day 10.

Statistical Analysis

Descriptive statistics were used for demographic data. Categorical variables were represented as frequency [n (%)] and analysed by chi chi-square test. The normality test of the Lysholm score data of both the groups was carried out; if the data was found to be in a normal distribution, then a parametric test (Student's t-test) was carried out whereas if the data was found to be in non-normal distribution, then non-parametric test (Mann-Whitney U test) was carried out. From the analysis of normality test, normal distribution data was represented as mean \pm SD and non-normal distribution data was represented as median with interquartile range. $p < 0.05$ was considered as statistically significant. Analysis of the data was done with the help of SPSS 18.0 software.

Results

As shown in Table 1, study data shows that the mean age of the patients operated with FLDs was 28.82 ± 8.76 years whereas the mean age of patients operated with ALDs was 28.35 ± 7.25 years. Two female

Table 1: Baseline Characteristics

	FLDs (n=17)	ALDs (n=17)	p value
Age (years) Mean \pm SD	28.82 \pm 8.76	28.35 \pm 7.25	0.86
Male, n (%)	15 (88.2)	16 (94.1)	0.36
Female, n (%)	2 (11.76)	1 (5.88)	0.54
Right side ACL tear, n (%)	9 (52.94)	9 (52.94)	0.11
Left side ACL tear, n (%)	8 (47)	8 (47)	1
Associated meniscus Injury	12 (70.58)	11 (64.70)	0.71

ACL: Anterior cruciate ligament; ALDs: Adjustment length loop devices; FLDs: Fixed length loop devices

Table 2. Assessment of Lysholm score at preoperative and at 1 month, 2 months, and 6 months follow-ups

		FLDs group (Mean±SD) (n=17)	ALDs group (Mean±SD) (n=17)	p value
Lysholm score	Preoperative	51.53±6.39	50.24 ±12.36	0.7
	Postoperative (1month)	75.53 ± 6.53	73.94 ± 6.74	0.49
	Postoperative (2 months)	89.35 ± 3.72	89.71 ± 3.53	0.77
	Postoperative (6 months)	97.94 ± 1.95	98.29 ± 1.86	0.59

ALDs: Adjustment length loop devices; FLDs: Fixed length loop devices

patients were present in FLD group and one female patient was present in the ALD group. Right Right-sided ACL tear (52.94%) was common in both the groups.

Meniscus injury was associated in both the groups, 70.58% and 64.70% in FLD and ALD groups, respectively.

It was observed that the mean Lysholm score of patients belonging to FLDs group were 51.53 ± 6.39, 75.53 ± 6.53, 89.35 ± 3.72, 97.94 ± 1.95 and the patients belonging to ALDs group were 50.24 ± 12.36, 73.94 ± 73.94, 89.71 ± 3.53, 98.29 ± 1.86 at preoperatively and then postoperatively at one, two and six months, respectively. There was no statistical significance difference found in between the groups at preoperatively and then postoperatively at one, two, and six months (p>0.05) (Table 2, Figure 1).

Preoperatively pivot shift test showed that the patients belonging to FLDs group with grade 3 and grade 2 instability were 41.17% and 58.82%, respectively. Preoperatively the patients belonging to ALDs group with grade 3 and grade 2 instability were 35.29% and 64.7%, respectively (Table 3). Analysis showed no significant difference was observed in between the groups (p>0.05). As shown in Table 3, it was observed that the Pivot shift test of patients belonging to the FLDs group with no instability and grade 1 instability was 94.11% and 5.88%, respectively at six months postoperatively. The patients belonging to the ALDs group with no knee instability and grade 1 instability were 82.35% and 17.64%, respectively at six months postoperatively. Analysis showed no significant difference was found in between the groups at six months post

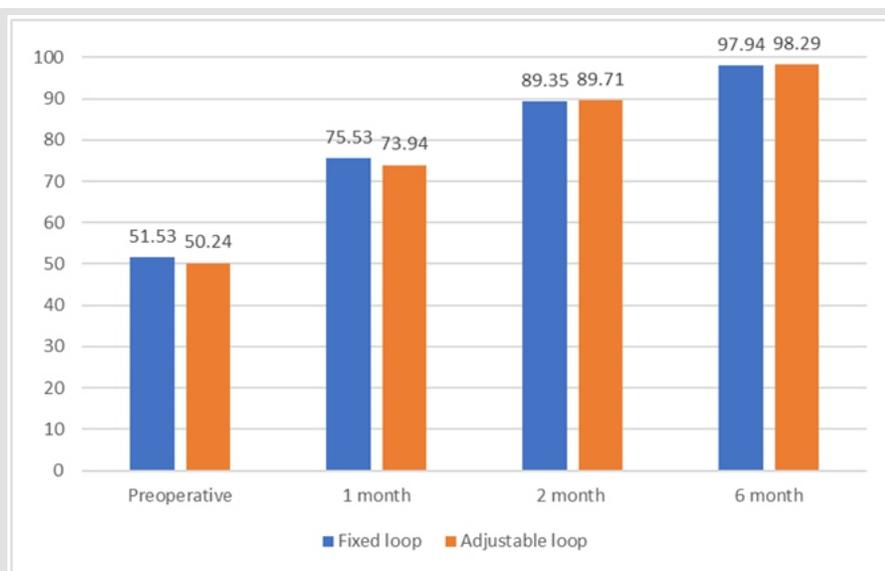


Figure 1: Mean Lysholm score of patients in both groups

Table 3. Assessment of Pivot shift test at preoperatively and 6 months postoperatively

Grade	FLDs group (n = 17)	ALDs group (n = 17)	p value
Pivot test (preoperative)			
Negative	0	0	0.72
1	0	0	
2	10 (58.82)	11 (64.70)	
3	7 (41.17)	6 (35.29)	
Pivot test (postoperative at 6 months)			
Negative	16 (94.11)	14 (82.35)	0.28
1	1 (5.88)	3 (17.64)	
2	0	0	
3	0	0	

ALDs: Adjustment length loop devices; FLDs: Fixed length loop devices

Table 4. Assessment of Lachman test at preoperatively and 6 months postoperatively

Grade	FLDs group (n = 17)	ALDs group (n = 17)	p value
Lachman test (preoperatively)			
Negative	0	0	0.48
1	0	0	
2	11 (64.70)	9 (52.94)	
3	6 (35.29)	8 (47.05)	
Lachman test (postoperatively at 6 months)			
Negative	15 (88.23)	14 (82.35)	0.62
1	2 (11.76)	3 (17.64)	
2	0	0	
3	0	0	

ALDs: Adjustment length loop devices; FLDs: Fixed length loop devices

operatively ($p>0.05$).

Table 4 shows that at six months postoperatively, no laxity and grade 1 laxity was observed in 88.23% and 11.76%, respectively in FLDs group on the Lachman test; whereas no laxity and grade 1 laxity was observed in 82.35 % and 17.64% of patients, respectively, in patients belonging to ALD group. Analysis showed that there was no significant difference between the groups at six months postoperatively ($p>0.05$).

Discussion

The most important outcome of this study is that the short-term clinical outcome of arthroscopic ACL reconstruction using FLD and ALD for femoral fixation are similar in terms of postoperative Lysholm score, Pivot shift test, and Lachman test. ALDs are “one loop size fits for all” femoral tunnel sizes thus avoiding the over the drilling of the femoral tunnel and the need to calculate loop length, thereby avoiding multiple loop sizes in the inventory. These also provide intra-operative flexibility of tensioning the graft after tibial fixation to remove any excessive laxity, depending on the graft length and the tibial tunnel length. These factors may minimize graft micro motion, femoral tunnel widening, and eventual graft failure. A meta-analysis has concluded that femoral tunnel widening is more common with cortical button fixation against a transfemoral cross pin fixation and this may be due to the Bungee effect and windshield wiper effect loop [12]. However, there have been concerns about the tendency of ALDs to lengthen under cyclical load and thus compromising effective graft length [8]. This is crucial during the early phase of rehabilitation, when there is graft incorporation in the bony tunnel. Any lengthening of graft at this stage would affect not only the tendon tendon-bone healing but also lead to knee instability. Lengthening of graft due to an increase in the size of the loop more than 3 mm (elongation or side-to-side difference) is the criterion for the failure of the graft [12]. Biomechanical studies have shown that ALDs have tendency to lengthen under cyclic loads because the free suture ends are pulled into the adjustable loop [9, 13, 14].

In 2014, Watson performed a review of four articles. All of these studies used cyclic loading to assess the mechanical properties of ALDs vs FLDs devices in the range deemed normal for a normal ACL executing basic activities of daily living. It was observed that FLDs caused considerably less displacement and had a greater tensile strength than ALDs. The study concluded that after being adjusted to their minimal length, ALDs might slide and lengthen under load, potentially causing delayed graft healing and joint instability [13, 14].

All the biomechanical studies have reported satisfactory pull to failure strengths for ALD and FLD. The maximum loads at failure under cyclic loading were reported by Noonan et al where it was found that a failure load more than the loads of 150–590 N that have been estimated across the ACL in the early rehabilitation period [14, 15]. Most biomechanical studies reported that ALDs when subjected to increase load cyclic loading behaved less favourably (in terms of lengthening) than FLDs. In some studies, ALDs lengthened more than 3 mm, which was a cause for concern. They also tend to do poorly under lower loads, perhaps due to the “unlocking” of their adjustable mechanism [15, 16]. Re-tensioning and knot tying in most studies were found to improve the properties of adjustable loops, although researchers have noted the challenging nature of knot tying in live surgeries. Various studies covered a realistic spectrum of loading forces that are constructed ACL grafts might be expected to experience [15, 16].

Some of the other studies have evaluated the functional outcomes of ACL reconstruction using FLDs and ALDs. The final outcome of

Lysholm score at 6 months postoperatively in our study for FLDs were 97.94 ± 1.95 and for ALDs were 98.29 ± 1.86 . Our study showed no significant difference in the functional outcome between the groups ($p>0.05$). The mean value of the Lysholm score was higher in our study than in other studies as shown in Table 5.

There was an improvement in the stability of knee as assessed by Lachman's test and Pivot shift test at 6 months in both the groups but the difference was found to be statistically insignificant ($p>0.05$). On final-follow with Pivot shift test, three patients had grade 1 instability with ALD and one patient had grade 1 instability with FLD. On final follow-up at six months postoperative, our study found that three patients had grade 1 laxity with ALD and two patients had grade 1 laxity with FLD on the Lachman test. All patients demonstrated excellent results on Lysholm score. There was no significant difference in the outcome of both the groups ($p>0.05$). Similar findings were in line with other studies (Table 5) [16–20, 17-21]. The outcomes of all these studies indicate that the ability of both methods of fixation are comparable and provide comparable stability to the knee.

Meniscus injury was commonly present with the ACL injury in both the groups of patients. Meniscus injury in the majority of patients was treated by partial meniscectomy. The presence of meniscus injury did not affect the in outcome of patients with ACL reconstruction with FLDs and ALDs. The postoperative protocol for rehabilitation was the same for ACL reconstruction with FLDs and ALDs with or without meniscus injury. Same The same physiotherapy protocol was used during the postoperative period in both the groups with or without meniscus injury. The outcomes of the current study shows that both modes of cortical suspension devices for ACL reconstruction showed improved function as demonstrated by the increase in Lysholm score. Stability of knee joint in both groups improved as demonstrated by Pivot shift test and Lachman test. The differences among both modes of femoral fixation were not statistically significant. Studies that reported clinical outcomes like the Lachman test and Pivot shift test for comparing between FLDs and ALDs were limited. However, our findings supports the findings of previous studies which showed similar outcomes [17, 18, 19, 21, 22].

There were few limitations of the study. No randomization was done for patient selection and short-term follow-up. The subjective method was used to assess stability. Subjectively measured outcomes can be inconsistent and there can be interobserver differences; subjective clinical assessment to determine graft failure may be less clinically important compared with the objective measures. Objective measures like KT-1000 arthrometer measurements were not used for assessment. However, future studies with long-term follow-up are required to confirm the results.

Conclusion

FLDs and ALDs cortical suspension devices are equally effective in femoral fixation of graft in ACL reconstruction. Functional outcomes in both the groups were comparable in terms of Lysholm score and knee stability using the Pivot shift test and Lachman test. Clinical outcomes of ACL reconstruction for femoral fixation using FLDs and ALDs were found to be similar.

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Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

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