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RESEARCH ARTICLE

Adjustable Versus Fixed Loop Devices For Femoral Fixation In Acl Reconstruction

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ABSTRACT

Suspensory devices are widely used in the management of anterior cruciate ligament (ACL) tear. They include fixed- and adjustable-loop devices. The aim of this study is to compare clinical and functional outcomes between the adjustable loop device (group I) and fixed-loop device (group II). Methodology: This was a prospective randomized study. Both groups were equivalent in demographic, preoperative, and intraoperative variables. Thirty patients underwent femoral side graft fixation with adjustable-loop and thirty with fixed-loop devices. Assessment of clinical outcome was done with Lysholm score, and knee stability tests (Lachman test, anterior drawer's test and pivot shift test). Patient evaluation was performed preoperatively and 12 months after surgery. Result: No significant differences were observed between Group A (Adjustable Loop) and Group B (Fixed Loop) in terms of age, injury duration, preoperative MRI findings, postoperative knee function, or Lysholm scores ($p>0.05$). Both groups showed similar outcomes in knee stability and rehabilitation progress, with minor complications and no significant differences in the need for additional interventions. Conclusion:There were no significant differences in graft laxity or functional outcomes between fixed- and variable-loop devices after ACL reconstruction, though the variable-loop group reported higher patient-reported outcomes at six weeks, warranting further clinical research.

Keywords: Adjustable loop, fixed loop, ACL, Laxity.

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INTRODUCTION

The ACL and PCL are the key cruciate ligaments in the knee, with the ACL playing a vital role in stabilizing the joint against translation and rotational stresses[1.] The ACL, an intracapsular and intra-articular structure, prevents anterior tibial translation over the femur and aids in movements like going downstairs. ACL injuries, often caused by hyperextension, are common and can lead to knee instability, osteoarthritis, and meniscus tears, with the O'Donoghue Triad referring to combined ACL, MCL, and medial meniscus tears[2] .Athletes, particularly females, are more prone to ACL ruptures due to factors like hormones, anatomy, and neuromuscular control, with effective prevention programs focusing on proprioception, strength training, and proper movement techniques. ACL reconstruction, typically using an autologous graft, aims to stabilize the knee for return to sports and prevent recurrence, with surgical fixation using a loop endobutton and bioabsorbable screws. A thorough medical history, physical exams (e.g., Anterior Drawer, Lachman, and Pivot Shift tests), and MRI imaging are essential for diagnosing ACL tears and assessing the degree of injury. There are two main types of grafts for ACL reconstruction:

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autografts and allografts, with allografts carrying risks like disease transmission and higher costs. Common autografts include Hamstring (ST & G), Patellar Tendon (BPTB), and Peroneus Longus, with BPTB grafts posing risks like patellar fractures and knee weakness, while hamstring grafts offer mechanical strength and fewer donor site complications[3]. Methods that enable the hamstring tendon grafts to be multiplied by two or even four enhance the graft's initial tensile strength and expand its cross-sectional diameter, which has to be at least 7 mm. Moreover, Hamstring is a suitable source for autograft used in ACL restoration[4]. ACL reconstruction typically takes 6-8 months to regain full strength, with success measured by various scoring systems (e.g., IKDC, WOMAC), and the graft fixed using methods like interference screws or loop devices[5,6] .When using the FLDs, there is the need for an additional drilling depth for button flipping, which results in extra femoral bone loss. Therefore, the ALDs designed with an adjustable loop allowing for loop re-tensioning after graft insertion and adjustment of the loop's length[7]. This provides surgical advantages that potentially lead to reduced bone removal[8], reduced femoral tunnel widening[9], and improved graft healing[10]. Biomechanical studies found ALDs to be inferior to FLDs in terms of maximum displacement after cyclic loading and stifness[11-14]. In contrast, clinical studies reported similar knee laxity and patient-reported outcome measures between ALDs and FLDs[15].

METHODOLOGY

This was a hospital-based prospective study conducted in the Department of Orthopaedics at Sardar Patel Medical College, Bikaner, with a study duration of 1.5 years. The study focused on patients with ACL injuries. Inclusion criteria consisted of patients aged 18 to 50 years who had ACL injuries that failed to respond to conservative treatments. Exclusion criteria included: ACL ruptures associated with tibial or femoral condyle fractures, tibial spine avulsion fractures, or reconstruction using different femoral fixation methods; other ligament injuries (PCL, MCL, LCL) or meniscus injuries; evidence of osteoarthritis on plain radiographs; and a history of prior surgery or cruciate ligament damage in the affected knee.

Sampling technique and sample size

Consecutive sampling was done. Patients were chosen randomly in both the study groups (Either Adjustable loop group or fixed loop group)

As per study of Alqarni FS et al.96reported prevalence of ACL injury was 14.5% with 95% Confidence interval and by taking 10% error minimum sample size was 48 and after taking 10% non-responses and round off to the minimum sample to 60 cases. Thus we will take Minimum 30 cases in each group as of 30 cases of ACL to treat with ALD method and 30 cases with FLD method.

Formula used to estimate sample size

N=Z2 p (1-p)/d2

N= (1.96)2 x 14.5 x (100-14.5) / 102 = 48

Here

N= Number of sample size

Z = Is standard normal variate (at 95% confidence interval it is 1.96).

p = Expected proportion in population based on previous studies (14.5% as per previous article)96

d = Absolute error (10%)

Statistical analysis

Descriptive statistical measures (mean, median, standard deviation and range) were estimated for summarizing the quantitative characteristics related to demographic variables.

Student's t test was applied for all quantitative measures and Chi-Square Test was applied for qualitative variables.

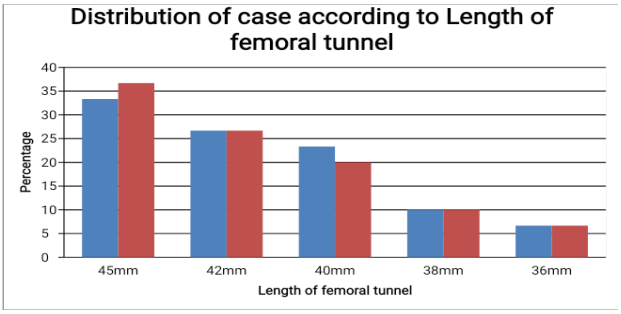
The two-sided $p< 0.05$ was considered statistically significant.

The data analysis was performed by using primer version 6.0.

RESULT

In group A maximum 46.67% were in 26 – 30 yr age group and 53.33% were in group B. The mean age of group A was 27.16 ± 4.53 whereas 27.83 ± 7.86 in group B. ($p>0.05$)

We also observed all cases according to duration of injury, in group A maximum 53.33% presented with in 1-6 months of complaints started followed by 20.00% cases after 7 – 12 months whereas in group B maximum 50% presented after 1-6 months of complaints followed by 36.67% after 7-12 months. The mean duration of injury at



Graph 1: Length of femoral tunnel and hamstring tendon graft

Table 1: Age Distribution

Age Group	*Group A*		*Group B*	
	No.	*%*	*No.*	*%*
18-25 years	05	16.67	4	13.33
26-30 years	14	46.67	16	53.33
31-40 years	10	33.33	9	30.00
>40 years	01	3.33	1	3.33
Total	30	100	30	100
Mean ± SD	27.16 ± 4.53		27.83 ± 7.86	
P value	0.687			

Table 2: Distribution of case according to duration of injury

Duration of injury (months)	*Group A*		*Group B*	
	No.	*%*	*No.*	*%*
1 – 6	16	53.33	15	50.00
7 – 12	10	33.33	11	36.67
>12	4	13.33	4	13.33
Total	30	100	30	100
Mean	6.56 ± 3.78		6.83 ± 4.45	
P value	0.961			

Table 3: Postoperative knee bending

Knee bending (in degrees)	*Group A*		*Group B*	
	No.	*%*	*No.*	*%*
140^0 (normal)	18	60.00	19	63.33
130^0	6	20.00	5	16.67
120^0	4	13.33	3	10.00
$<120^0$	2	6.67	3	10.00
P value	0.786			

Table 4: Lysholm's knee scoring scale at 12 months

Lysholm's knee scoring scale	*Group A*		*Group B*	
	No.	*%*	*No.*	*%*
Excellent (91 - 100)	13	43.33	16	53.33
Good (84 - 90)	12	40.00	10	33.33
Fair (65 - 83)	4	13.33	3	10.00
Un satisfactory (<64)	1	3.33	1	3.33
Mean	85.16	5.49	88.25	5.011
P value	0.026**			

the time of presentation was 6.56 ± 3.78 months in group A whereas 6.83 ± 4.45 months in group B. (p>0.05)

we found that the minimum length of the femoral tunnel was 36mm in 2 cases in both groups and the maximum length was 45 mm in 10 cases in group A and 11 cases in group B. Mean length of femoral tunnel was 39.64± 2.12 mm in group A and 39.68 ± 2.13mm in group B. we found that the length of the hamstring tendon was sufficient. On five layered the graft the length was between 9cm- 10 cm. The mean length of the fiver graft was 9.4 cm in group A and 9.5 cm in group B.

In our study on follow up, we found that knee stiffness increases after ACL reconstruction as 6 (20%) case in group A and group B had decrease range of knee movement.

When we compared both groups according to Lysholm's knee scoring scale, the mean score was 85.16 ± 5.49 in group A was lower than 88.25 ± 5.01 in group B.

Maximum 43.33% had excellent score in group A and 53.33% in group B whereas minimum 3.33% had unsatisfactory score in both groups.

DISCUSSION

In group A maximum 46.67% were in 20 – 29 yr age group and 53.33% were in controls. The mean age of group A was 27.16 ± 4.53 whereas 27.83 ± 7.86 in group B.Manish Shukla et al. (2023)[16] There was no significant difference in mean age between Adjustable Loop and Fixed loop groups. The mean age among Adjustable Loop was 35.20±3.88 years, Fixed loop was 33.42±4.80 years and Over-all was 34.31±4.43 years.

In our study, we observed that maximum 60% had left limb affected in group A whereas 63.33% in group B. (p>0.05).

We also observed all cases according to duration of injury. The mean duration of injury at the time of presentation was 6.56 ± 3.78 months in group A whereas 6.83 ± 4.45 months in group B. (p>0.05).Sebastian Schützenberger et al. (2022)[17] The groups were homogenous at baseline regarding age, gender, and the time to surgery. As the fixed-loop technique was gradually replaced by the adjustable-loop technique the time to follow-up was significantly shorter in the AL group.

In our study, when we examine the cases by Lachman test we found that in group A maximum 43.33% cases had 1+ score, 36.67% had 2+ and 13.33% had 3+ score whereas in group B maximum 46.67% cases had 1+ score, 36.67% had 2+ and 6.67% had 3+ score. The test was negative in 6.67% in group A whereas 10% in group B. (p>0.05) Similarly Naiyer Asif et al. (2021)[18] In group I, 6 patients (26%) had positive Lachman grade 2 and 16 patients (69.7%) had positive grade 3, whereas in group II, 5 patients (25%) had grade 2 and 14 patients (70%) had grade 3 instability (p = 0.9).

In our study, when we examine the cases by Anterior drawer test we found that in group A maximum 26.67% cases had 1+ score, 23.33% had 2+ and 6.67% had 3+ score whereas in group B maximum 30.00% cases had 1+ score, 26.67% had 2+ and 3.33% had 3+ score. The test was negative in 43.33% in group A whereas 40.00% in group B. (p>0.05), When we examine the cases by pivot shift test we found that in group A maximum 53.33% cases had positive test whereas in group B 50.00% cases. The test was negative in 46.67% in group A whereas 50.00% in group B. (p>0.05). Naiyer Asif et al. (2021)[18] observed that Pivot shift test was grade 2 in 13 patients (56.5%) and grade 3 in 8 patients (34.8%) in group I; however, in group II it was grade 2 in 11 patients (55%) and grade 3 in 7 (35%) patients (p = 0.9).

In the preoperative MRI we found that 17 (56.67%) cases in group A and 18 (60%) cases in group B were reported to have mid-substance tear of ACL, 8 (26.67%) cases in group A and 9(30% cases) in group B were reported to have avulsion from the tibial attachment site and 5 (16.67%) cases in group A and 3 (10%) in group B were reported to have avulsion from the femoral attachment site. (p>0.05). Preoperative MRI found 26 in group A and 25 cases in group B to have sufficient intercondylar notch. (p>0.05) Similarly Manish Shukla et al. (2023)[16] observed that there was no signicant difference in type of injury between Adjustable Loop and Fixed loop groups. The most common type of injury was lateral (41.0%) followed by medial (39.0%) and Dual (10.0%).

On arthroscopic survey synovitis was noted in 3 cases in group A and B each. It was found that 16 (53.33%) cases in group A and 17 (56.67%) cases in group B were reported to have mid-substance tear of ACL, 9 (30%) cases in group A and group B each were reported to have avulsion from the tibial attachment site and 5 (16.67%) cases in group A and 4 (13.33%) in group B were reported to have avulsion from the femoral attachment site.

In our study we found that the Mean length of femoral tunnel was 39.64± 2.12 mm in group A and 39.68 ± 2.13mm in group B. We found that the length of the hamstring tendon was sufficient.

In our study we found that 18 (60%) case in group A and 19 (63.33%) cases in group B had normal range of knee movement. (p>0.05) On follow up, we found that knee

stiffness increases after ACL reconstruction as 6 (20%) case in group A and group B had decrease range of knee movement (1200).

When we examine the cases by Lachman test (postoperative) we found that in group A 10% cases had 1+ score, 3.33% had 2+ and 3+ score each whereas in group B only 13.33% cases had 1+ score. The test was negative in 83.33% in group A whereas 86.67% in group B.

When we examine the cases by Anterior drawer test we found that in group A maximum 6.67% cases had 1+ score, 3.33% had 2+ and 3+ score each whereas in group B only 6.67% cases had 1+ score. The test was negative in 86.67% in group A whereas 93.33% in group B. Similarly Naiyer Asif et al. (2021)[18] in their study observed that final clinical and functional assessments of all patients were done 2 years after the surgery. There were three patients in each group who had positive Lachman's grade 1 ($p = 0.8$); however, pivot shift grade 1 was present in one patient in each group ($p = 0.9$).

In group A maximum 20% had knee stiffness followed by 10% effusion and 3.33% haemarthosis whereas in group B 16.67% had knee stiffness and 10% had effusion.

In group A one case was reopened for Arthroscopic lavage, no cases in group B needed such interventions. Similarly Sebastian Schützenberger et al. (2022)[17] found that one patient had an early postoperative infection and was successfully treated with arthroscopic lavage.

In our study, when we compared both groups according to Lysholm's knee scoring scale, the mean score was 85.16 ± 5.49 in group A was lower than 88.25 ± 5.01 in group B. Similarly Manish Shukla et al. (2023)103 The mean Lysholm knee score post-operative at 9 months in CLF group was 89.44 ± 6.22 and in ALF group was 93.90 ± 5.40. There were no statistically significant differences. Also Sebastian Schützenberger et al. (2022)[17] The mean Lysholm score was 89.9 ± 11.0 in the FL group and 87.3 ± 12.1 in the AL group ($p = 0.380$).

CONCLUSION

The laxity of the graft and functional results after arthroscopic ACL reconstruction with fixed- and variable-loop devices were not significantly different, with the exception of a higher patient-reported outcome score in the variable-loop group at six weeks of follow-up. There was no difference in the device's displacement between the two groups in our study, despite the fact that several biomechanical studies have indicated that variable-loop devices exhibit higher displacement than fixed-loop designs. Therefore, there is a need for further clinical comparison research in this area.

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