

A Comparative Study on Functional Outcomes of Fixed Versus Adjustable Length-Loop Device for Femoral Fixation of Graft in Anterior Cruciate Ligament Reconstruction

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Abstract

Background: ACL injury is one of the most common injuries of knee among high level athletes and also common in young and non sports people [1]. Intra-articular anatomical ACL reconstruction (ACLR) with a biologic graft has become the gold standard for the treatment of ACL tear. The use of the semitendinosus and gracilis (STG) tendons is becoming the choice method in anterior cruciate ligament (ACL) reconstruction [1]. Cortical suspensory fixation is the current preferred Femoral fixation method and is in wide spread use [2]. Cortical suspension device available in two varieties 1. Fixed Loop-Length device (FLD) e.g. Endobutton; 2. Adjustable Loop-Length device (ALD) e.g. Tightrope, Toggleloc, ZipLoop. We conducted this prospective study to find out which device fared better in terms of functional outcomes and laxity measurements at a final follow up of 1 year.

Material and Methods: This is prospective study conducted in the PG Department of Orthopaedics in S.C.B Medical College & Hospital from June 2018 to February 2020. There were 53 patients included in our study. All patients presenting with history of trauma to the knee in the orthopaedics emergency and outpatient departments in SCB Medical College were evaluated by a thorough general and local examination of the knee. Routine radiographs in antero-posterior view and lateral view of the affected knee were taken. MRI of the knee was done in all suspected ACL torn cases for confirmation. Patients who have chosen to undergo ACL repair surgery are then randomly selected and allocated to two groups, group 1 are the patients operated with fixed loop suspension devices and group 2 patients are operated with adjustable loop suspension devices. All patients underwent ACLR with 4 strand, autologous hamstring grafts and fixed in the tibial side with a bio-degradable interference screw.

Study Center: SCB Medical College & Hospital, Cuttack between June 2018- February 2020.

Results: Tegner Lysholm Score shows no difference between both the groups at any point of time. At last follow up of 12 months the Tegner Lysholm score was 93.05 ± 4.04 in fixed loop group and 92.81 ± 2.96 in adjustable Loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.726, 0.572 and 0.805 respectively. KOOS Score for pain shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 91.86 ± 3.73 in fixed loop group and 91.79 ± 3.46 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.545, 0.490 and 0.949 respectively. KOOS Score for symptoms shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for symptoms was 95.90 ± 3.73 in fixed loop group and 96.16 ± 3.46 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.968, 0.626 and 0.797 respectively. KOOS score for activities for daily living shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for activities for daily living was 91.59 ± 2.49 in fixed loop group and 91.22 ± 1.99 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.757, 0.566 and 0.549 respectively. KOOS score for sports and recreations shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 85.00 ± 6.54 in fixed loop group and 85.65 ± 7.15 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.545, 0.781 and 0.739 respectively. KOOS score for quality of life shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 86.64 ± 9.10 in Fixed loop group and 88.30 ± 7.17 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.876, 0.790 and 0.462 respectively.



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Conclusions: Arthroscopic ACL reconstruction using fixed loop or adjustable loop suspensory devices are equally effective fixation alternatives. It gives equal functional outcome in both cases, in terms of Tegner-Lysholm score & Knee-injury & Osteoarthritis Outcomes Score. Proper technique with appropriate tunnel positioning are the main factors of ACL reconstruction. Although many in vitro studies have shown that adjustable loop devices are biomechanically inferior to fixed loop devices, previous clinical studies as well as our study fail to corroborate this. The logical step forward would be to conduct well designed Randomized Control Trials comparing the two devices. Until further evidence clearly shows the superiority of one device over the other, it can be expected to yield similar results.

Keywords: ACL reconstruction, Adjustable length loop device, Fixed loop device

Introduction

ACL injury is one of the most common injuries of knee among high level athletes and also common in young and non sports people [1]. Intra-articular anatomical ACL reconstruction (ACLR) with a biologic graft has become the gold standard for the treatment of ACL tear. The use of the semitendinosus and gracilis (STG) tendons is becoming the choice method in anterior cruciate ligament (ACL) reconstruction [1]. Cortical suspensory fixation is the current preferred Femoral fixation method & is in wide spread use [2]. Cortical suspension device available in two varieties

1. Fixed Loop-Length device (FLD) e.g. Endobutton
2. Adjustable Loop-Length device (ALD) e.g. Tightrope, Toggleloc, ZipLoop.

Fixed Length Loop Device:

Advantages:

- Biomechanically proven to be superior.
- Less elongation on cyclic loading.

Disadvantages:

- Potentially greater graft motion in tunnel due to over drilling.
- Needs exact tunnel measurements.

Adjustable Length Loop Device:

Advantages:

- Does not require any intra operative calculations.
- Can be used in shorter tunnel also.
- Graft can be tensioned even after flipping.
- Whole of the socket filled with graft, potentially eliminating graft motion.

Disadvantages :

- Biomechanically proven to be inferior.
- Potential for elongation during cyclic loading, leading to loss of graft tension.

Aim of Study

To study the comparison between functional outcomes of fixed loop and adjustable loop cortical suspensory devices for femoral fixation in arthroscopic ACL reconstruction using Tegner-Lysholm Knee Scoring scale and Knee-injury & osteoarthritis Outcomes Score (KOOS) up to 12 months post operatively.

Materials & Methods

Source of Data: This is prospective study conducted in the PG Department of Orthopaedics in S.C.B Medical College & Hospital from June 2018 to February 2020. There were 53 patients included in our study. All patients presenting with history of trauma to the knee in the orthopaedics emergency and outpatient departments in SCB

medical college were evaluated by a thorough general and local examination of the knee. Routine radiographs in antero-posterior view and lateral view of the affected knee were taken. MRI of the knee was done in all suspected ACL torn cases for confirmation.

Inclusion Criteria:

- Clinical/MRI evidence of symptomatic individuals with ACL insufficiency.
- Age group between 18 to 40 years.
- A normal contra lateral knee.
- Patients who give informed consent and willing for follow-up.
- Cases of ACL injury medically fit for surgery.
- Patients with closed injuries

Exclusion Criteria:

- Patients treated with other than cortical suspension devices.
- Patients less than 18 years of age & more than 40 years.
- Patients unfit for surgery.
- Associated co-morbid conditions history of suffering from Myocardial Infarction (MI) less than 1 year, psychiatric illness, head injury etc.
- Uncontrolled Diabetes mellitus, Hypertension, Patients with clinically detectable focus of active infection.
- Involving other than ACL injury, bony fracture and neurovascular injury.
- Revision ACL reconstruction.
- History of previous surgery in the knee.

Patients who have chosen to undergo ACL repair surgery are then randomly selected and allocated to two groups, group 1 are the patients operated with fixed loop suspension devices and group 2 patients are operated with adjustable loop suspension devices. All patients underwent ACLR with 4 strand, autologous hamstring grafts and fixed in the tibial side with a bio-degradable interference screw.

Surgical Technique



Figure 1: Marking of portals and skin incision



STG graft is harvested incising sartorius fascia



Quadrupled STG graft attached with fixed loop device



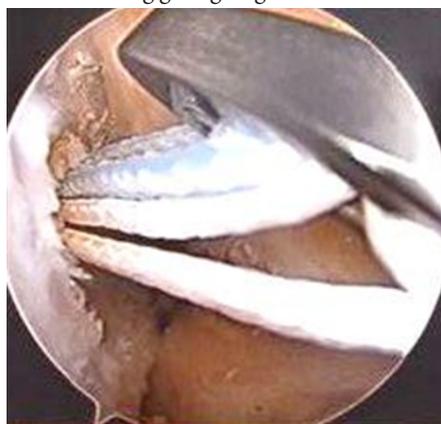
Prepared adjustable loop with pretensioning of graft



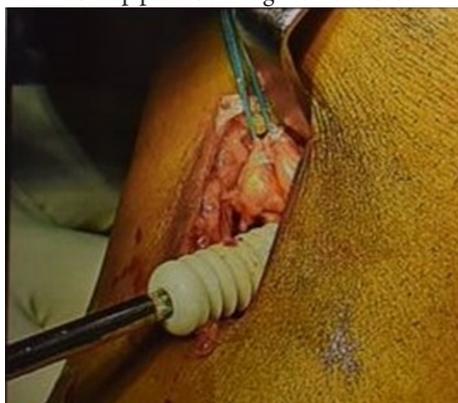
Outside view showing graft going from anteromedial side



Fixed loop pulled through femoral side



Adjustable loop pulled through femoral side



Tibial side graft fixation through Bio-screw



Post-op X-Ray

Post-Operative Evaluation

- All patients were evaluated post-op 3 months, 6 months and 12 months follow-up.
- Knee-injury and osteoarthritis outcomes score (KOOS)
- Tegner-Lysholm knee scoring scale

Results

	Mean score of FLD group	Mean score of ALD group	P value
Pre-operative Tegner-Lysholm	53.59 ± 6.38	51.39 ± 8.31	0.302
Post-operative Tegner-Lysholm at 3 months	84.18 ± 6.33	83.58 ± 5.95	0.726
Post-operative Tegner-Lysholm at 6 months	89.59 ± 5.67	88.71 ± 5.46	0.572
Post-operative Tegner-Lysholm at 12 months	93.05 ± 4.04	92.81 ± 2.96	0.805

Tegner Lysholm Score shows no difference between both the groups at any point of time. At last follow up of 12 months the Tegner Lysholm score was 93.05 ± 4.04 in fixed loop group and 92.81 ± 2.96 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.726, 0.572 and 0.805 respectively.

KOOS Score for pain shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 91.86 ± 3.73 in fixed loop group and 91.79 ± 3.46 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.545, 0.490 and 0.949 respectively.

	Mean score of FLD group	Mean score of ALD group	p value
Pre-operative KOOS-Pain	66.36 ± 5.49	66.15 ± 5.68	0.894
Post-operative KOOS-Pain at 3 months	76.73 ± 6.72	75.49 ± 7.64	0.545
Post-operative KOOS-Pain at 6 months	85.05 ± 5.38	83.85 ± 6.62	0.49
Post-operative KOOS-Pain at 12 months	91.86 ± 4.20	91.79 ± 3.93	

KOOS Score for symptoms shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for symptoms was 95.90 ± 3.73 in fixed loop group and 96.16 ± 3.46 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.968, 0.626 and 0.797 respectively.

	Mean score of FLD group	Mean score of ALD group	p value
Pre-operative KOOS-symptoms	55.63 ± 8.51	56.40 ± 9.10	0.756
Post-operative KOOS-symptoms at 3 months	76.09 ± 7.57	75.99 ± 10.55	0.968
Post-operative KOOS-symptoms at 6 months	89.22 ± 4.80	90.04 ± 6.69	0.626
Post-operative KOOS-symptoms at 12 months	95.90 ± 3.73	96.16 ± 3.46	0.797

	Mean score of FLD group	Mean score of ALD group	p value
Pre-operative KOOS- ADL	47.55 ± 8.06	47.68 ± 7.09	0.951
Post-operative KOOS- ADL at 3 months	70.55 ± 8.18	71.20 ± 7.08	0.757
Post-operative KOOS- ADL at 6 months	85.33 ± 2.47	84.92 ± 2.51	0.566
Post-operative KOOS- ADL at 12 months	91.59 ± 2.49	91.22 ± 1.99	0.549

KOOS Score for Activities for Daily Living shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for activities for daily living was 91.59 ± 2.49 in fixed loop group and 91.22 ± 1.99 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.757, 0.566 and 0.549 respectively.

KOOS Score for sports and recreations shows no difference

	Mean score of FLD group	Mean score of ALD group	p value
Pre-operative KOOS-sports and recreation	20.91 ± 5.26	20.32 ± 4.06	0.649
Post-operative KOOS-sports and recreation at 3 months	54.77 ± 9.06	56.45 ± 10.42	0.545
Post-operative KOOS-sports and recreation at 6 months	75.23 ± 9.19	74.52 ± 9.07	0.781
Post-operative KOOS-sports and recreation at 12 months	85.00 ± 6.54	85.65 ± 7.15	0.739

between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 85.00±6.54 in fixed loop group and 85.65 ± 7.15 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.545, 0.781 and 0.739 respectively.

KOOS Score for quality of life shows no difference between both the groups at any point of time. At last follow up of 12 months the KOOS score for pain was 86.64 ± 9.10 in fixed loop group and 88.30 ± 7.17 in adjustable loop group. The difference is not significant at 3 months, 6 months and 12 months with p values 0.876, 0.790 and 0.462 respectively.

	Mean score of FLD group	Mean score of ALD group	p value
Pre-operative KOOS-quality of life	42.89 ± 12.09	42.33 ± 11.49	0.865
Post-operative KOOS-quality of life at 3 months	68.46 ± 11.32	67.94 ± 12.36	0.876
Post-operative KOOS-quality of life at 6 months	79.26 ± 11.14	80.04 ± 9.87	0.79
Post-operative KOOS-quality of life at 12 months	86.64 ± 9.10	88.30 ± 7.17	0.462

Discussion

Cortical suspension device has been one of the most widely used for femoral fixation in ACL reconstruction. Controversy still exists whether fixed loop or adjustable length loop is better for femoral fixation [1]. In our study we found there was significant improvement in the clinical and functional status in both the group after operation.

But there were no clinically significant differences in outcome between the groups. Both the implant showed similar outcome whatever be their experimental advantages and disadvantages.

Dr. Bhanu Sharma and Dr. Rup Kumar Sharma in their prospective case series study analysed early outcomes of arthroscopic anterior cruciate ligament reconstruction using fixed closed loop and adjustable loop techniques and found that there were no significant differences in manual Lachman and Pivot shift grading in both groups. One case (5%) in CLF group and 15% in ALF group were showed Grade B clinically laxity by Lachman, and one case (5%) in CLF group and 10% in ALF group were showed Grade 2+ rotatory laxities by pivot shift. The study found no statistically significant differences in functional score between the groups ($P=0.245$). Hence in femoral fixation of ACL graft both closed loop fixation and adjustable loop fixation techniques may provide secure fixation, equal reduction of graft laxity, and similar functional outcome in ACL deficient knee [3].

B Pokhrel et al. in their comparative study on fixed versus adjustable length loop device for femoral fixation of graft in ACLR found that the average Tegner-Lysholm score before surgery in Endobutton group was 56.63 ± 6.7 and post op score at last follow up was 93.97 ± 4.1 and for Tightrope group it was 56.5 ± 7.1 and 94.7 ± 3.7 respectively. The average 2000 IKDC score before surgery in Endobutton group was 46.16 ± 6.1 and post op score at last follow up was 82.52 ± 4.2 and for Tightrope group it was 46.57 ± 6.5 and 83.98 ± 4.1 respectively. Two sample student t-test was conducted to compare the mean of post-operative Tegner-Lysholm score and 2000 IKDC for each group it showed p value for Tegner-Lysholm score to be 0.75 and that for 2000 IKDC score to be 0.7, which not statistically significant to reject the null hypothesis. Hence cortical suspension devices for femoral tunnel graft fixation are very efficient devices whether fixed-length or adjustable length. Fixed-length and adjustable loop cortical suspension devices are equally effective in femoral fixation of graft in ACL reconstruction [1].

Darby A. Houck et al. did a systematic review and meta analysis of Biomechanical studies on fixed versus adjustable loop femoral cortical suspension devices for ACLR. Six studies were identified that met the inclusion criteria, including total of 76 fixed loop devices and 120 adjustable loop devices. Load to failure was significantly different ($P < 0.0001$), with the strongest suggested that the Adjustable loop (Toggle Loc with Zip Loop) device is the strongest fixation device being the ToggleLoc with ZipLoop adjustable loop device (1443.9 ± 512.3 N), compared with the Endobutton CL fixed loop device (1312.9 ± 258.1 N; $p = 0.04$) and the TightRope RT adjustable loop device (863.8 ± 64.7 N; $p = .01$). Cyclic displacement was significantly different, with Endobutton CL (3.7 ± 3.9 mm) showing the least displacement, followed by ToggleLoc with ZipLoop (4.9 ± 2.3 mm) and TightRope RT (7.7 ± 11.1 mm) ($P < .0001$). Mode of failure was statistically different between the three groups ($p = .01$), with suture failure accounting for 83.8% of TightRope RT devices, 69.4% of ToggleLoc with ZipLoop devices, and 60.3% of Endobutton CL devices.

Hence the biomechanical data suggest that the ToggleLoc with ZipLoop device is the strongest fixation device at "time zero" in terms of ultimate load to mechanical failure. However, the fixed loop

(Endobutton CL) device demonstrated the least cyclic displacement, which may be a more clinically applicable measure of device superiority [4].

Eric McCarty et al. from their study found that the fixed-loop device, on average, displaced significantly less than the adjustable-loop devices. However, the adjustable-loop device demonstrated the highest ultimate load to failure [5].

Rahul Ranjan et al. in their in vivo prospective randomized study compared a fixed loop (Endobutton CL) with an adjustable loop (TightRope RT) for femoral fixation of graft in ACLR both groups were matched in terms of demographic, preoperative, intra operative and post-operative covarieties. EB ($n = 52$) appeared to have better IKDC and Lysholm scores at 6 months postoperative when compared to TR ($n = 50$). However, at a final follow up for 2 years, the results were similar. The anterior tibial translation and SSD were statistically insignificant between the two groups at 6 months and 2 years. Hence the study followed up of ACL reconstruction patients for 2 years revealed similar knee scores and laxity in the two groups (fixed loop fixation device and adjustable loop fixation devices [6].

SangHak Lee on editorial commentary stated that, to date, there is no consensus regarding which type of cortical suspension device is biomechanically superior for use during ACLR. In recent clinical studies, FLDs and ALDs yielded similar clinical outcomes and graft rerupture rates. With the advancement of intra operative imaging, further clinical studies that measure intra operative laxity are warranted. In addition, post operative serial MRI might be helpful to analyze loop slippage and graft displacement.

MF Ibrahim et al. compared fixed and adjustable loop fixation in ACLR for functional outcome found that independent t-test was statistically not significant at 12 months with the fixed loop fixation ($M = 93.82$, $SD = 0.307$) than the adjustable loop group ($M = 92.47$, $SD = 0.321$). Hence fixed and adjustable loop device shown no statistically difference in term of functional outcome at 12 months post operation [7].

Hardik Seth et al. proposed that arthroscopic ACLR using fixed loop and adjustable loop suspensory devices are equally effective fixation methods. Functional assessment was performed with VAS score, IKDC score and Lysholm score before and after surgery with ACLR. The post-operative Lysholm score in fixed loop group and adjustable loop group was 94.23 and 94.32 respectively. The IKDC score in fixed loop group and adjustable loop group was 92.03 and 92.16 respectively. VAS in fixed loop group improved from score of 5-3, while in adjustable loop group from score 4-3. There was significant improvement in stability of knee assessed by Lachman test, anterior drawer test, and Pivot shift test and both methods of fixation provide stability to knee. The complications included; restriction of terminal fixation in 12 patients: 6 in each group. There was no implant breakage in both groups [8].

Conclusion

Arthroscopic ACL reconstruction using fixed loop or adjustable loop suspensory devices are equally effective fixation alternatives. It gives equal functional outcome in both cases, in terms of Tegner-Lysholm score and Knee-injury and Osteoarthritis Outcomes Score. Proper technique with appropriate tunnel positioning are the main factors of

ACL reconstruction. Although many in vitro studies have shown that adjustable loop devices are biomechanically inferior to fixed loop devices, previous clinical studies as well as our study fail to corroborate this. The logical step forward would be to conduct well

designed Randomized Control Trials comparing the two devices. Until further evidence clearly shows the superiority of one device over the other, it can be expected to yield similar results.

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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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