Comparative study between adjustable and non-adjustable loop femoral fixation in cases of anterior cruciate ligament reconstruction

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The Egyptian Orthopedic Journal; 2020 supplement (1), June, 55: 63-69

Abstract

Introduction
There have been many devices introduced for fixation of soft tissue grafts during ACL reconstruction. However, there is still no gold standard technique for graft fixation.
Patients and Methods
A Prospective randomized study was carried out on 242 patients with torn ACL treated at El-Hadra University Hospital, Alexandria, Egypt, during the period from December 2015 to January 2018.
The patients were divided into two groups; group (A) included 129 patients who were fixed on the femoral side by endobutton and group (B) included 113 patients who were fixed on the femoral side by tightrope. All participants had signed an ethics committee approved consent form. All patients were analyzed using the International Knee Documentation Committee (IKDC) evaluation form, Lysholm score and visual analogue scale (VAS) score before and after arthroscopic ACL reconstruction.
Results
At two-year follow up, The IKDC score in fixed loop group (A) and adjustable loop group (B) was 93.09 and 92.31 respectively. The Lysholm score in fixed loop group (A) and adjustable loop group (B) was 94.39 and 93.72 respectively. VAS in fixed loop group (A) improved to 3.70, while in adjustable loop group (B) improved to 3.59.
Conclusion
Both groups showed no difference in stability in the last follow up (24-35 months in group A versus 24-38 months in group B).

Key Words
Anterior Cruciate Ligament, Fixed loop, endobutton, Adjustable loop, tightrope, IKDC, Lysholm, VAS.

Introduction

The fundamental philosophy of anterior cruciate ligament (ACL) reconstruction is to achieve accurate tunnel placement based on ACL anatomy on both the femoral and tibial side. [1 – 3] There have been many devices introduced for fixation of soft tissue grafts during ACL reconstruction. However, there is still no gold standard technique for graft fixation. [4 – 7]

The advances in the knowledge of anatomy, surgical techniques, and fixation devices have led to the improvement of ACL reconstruction over the past 10 years and become more popular. [8] Graft fixation is an important factor in ACL reconstruction especially in the first two months of healing during the process of ligamentization. So, the fixation must be strong enough to resist in vivo forces during this period. The strain on the ACL in a normal knee has been predicted to be approximately 700-800 N during intensive rehabilitation exercises and about 500 N during activities of daily living. Thus, any fixation-graft-fixation complex should be stronger than or exceeds this force experienced by the normal ACL during activities of daily living. [9 - 13]

There are multiple options for femoral fixation of a soft tissue graft in ACL reconstruction. First-generation cortical suspensory fixation buttons have fixed-length graft loops. An evolution of this cortical suspensory fixation button devices have led to development of second generation adjustable length loop devices as Tightrope. Second-generation buttons have graft loops that are adjustable in length, such that after the button flips and becomes fixed on the cortex, the graft loop may be tightened, pulling the graft into the socket in a manner that completely fills the socket with graft substance and allowing longer graft bone interface. Thus, ACL surgeons may increase graft tension after the graft is fixed. [14 - 16]

Advantages of adjustable suspensory femoral cortical fixation device (Tightrope) are elimination of the need for multiple implant sizes. Thus no need to calculate implant size and facilitates complete filling of the entire femoral socket with graft, making it ideal for short femoral tunnels that are common with anatomic ACL drilling. The length of the graft and the length of the femoral tunnel vary from patient to patient. It is important to get a good length of the graft material in both the tibia and femur so as to give the best chance of the graft healing to the surrounding bony tunnel wall. With the fixed loop system, once the metal button flipped on the outer cortex, the length of the loop cannot be adjusted. Thus the amount of hamstring graft in either end of the bony tunnel cannot be changed. One potential advantage of the adjustable loop system is that the amount of graft in either end of the bone tunnel can be altered to ensure sufficient graft is accurately placed.

Some technical difficulties could be encountered during ACL reconstruction using suspensory devices: flipping failure, jamming inside the femoral canal (endobutton), pulling too far off the lateral femoral cortex to the outside of the skin or iliotibial band (tightrope). Malpositioning of the tightrope may lead to either soft-tissue irritation or migration of the button with subsequent potential risk of graft laxity later that may lead to graft failure. This technical error can result in a worse clinical outcome.

Aim of the Work

The aim of the study was to investigate and compare the clinical and functional outcome of a fixed loop versus adjustable loop femoral suspensory devices in anterior cruciate ligament (ACL) reconstruction.

Patients and Methods

A Prospective randomized study was carried out on 242 patients with torn ACL treated at El-Hadra University Hospital, Alexandria, Egypt, during the period from December 2015 to January 2018.

The patients were divided into two groups; group (A) included 129 patients who were fixed on the femoral side by endobutton and group (B) included 113 patients who were fixed on the femoral side by tightrope. All participants had signed an ethics committee approved consent form.

The inclusion criteria included symptomatic patients with isolated ACL tear without other ligamentous injury. The only exception was patients suffering from small meniscal tears which were managed sufficiently via partial meniscectomy during the ACL reconstruction.

We excluded from this study patients with multi-ligamentous knee injuries, patients with previous knee surgery in the affected knee, patients with moderate to severe degenerative knee changes (radiologically), patients with knee mal-alignment, patients with a simultaneous sub-total meniscectomy involving 50% or more of the meniscus, and Patients with a neuromuscular deficiency.

The age of the patients of group (A) ranged from 23 to 38 years with a mean of 30.64 years; while in group (B) it ranged from 22 to 39 years with a mean of 31.35 years. Left knee was affected in 103 patients of group (A) and in 98 patients of group (B). The original knee injury was Pivoting non-contact sport during football playing in the majority of cases. The time interval between injury and operation ranged between 3 and 18 months in group (A) and between 3 and 17 months in group (B). (Table I).

Statistical analysis

Statistical analysis was undertaken using the statistical program for social sciences (SPSS) version 20.0 (IBM, Armonk, New York). Paired t tests and comparing means were used to analyze the relations between the obtained results in both groups. Chi square test was used to compare between two groups categorized data. Statistical significance was set at p=0.05.

Methods

Preoperative assessment included history and clinical tests including anterior drawer test, Lachman test and Pivot shift test were done. Radiological evaluation included plain radiography and magnetic resonance imaging (MRI) study for evaluation of the ACL and any associated internal derangement of the knee.

All patients were given spinal anaesthesia. Patients were laid supine with the affected knee flexed at the end of table, allowing knee flexion up to 120°. All patients were examined under anaesthesia to confirm the preoperative diagnosis.

The hamstrings tendons were harvested and prepared while preparation of tunnels was performed. Fig. 1

Table I: Demographic data of the patients of both groups

	Group A	Group B	P
Age			
Range	23-38	22-39	
Mean	30.64	31.35	**0.121**
S.D	4.63	4.98	
Side			
Left	103 (79.8%)	98(86.7%)	**0.078**
Right	26 (20.2%)	15(13.3%)	
Original knee injury			
Pivoting non-contact sport	82 (63.6%)	82 (72.5%)	
Contact sport	22 (17.0%)	14 (12.4%)	
Traffic	10 (7.8%)	8 (7.1%)	**0.122**
Work	8 (6.2%)	3 (2.7%)	
Activity of daily living	7 (5.4%)	6 (5.3%)	
Time interval between injury and operation (months)			
Range	3-18	3-17	
Mean	10.39	9.67	**0.093**
S.D	4.27	4.15	
Operative time			
Range	45.0-60.0	50.0-60.0	
Mean	52.3	55.6	**0.685**
S.D	10.6	4.65	
Follow up period			
Range	24-35	24-38	
Mean	31.0	32.5	**0.522**
S.D	6.21	7.21	

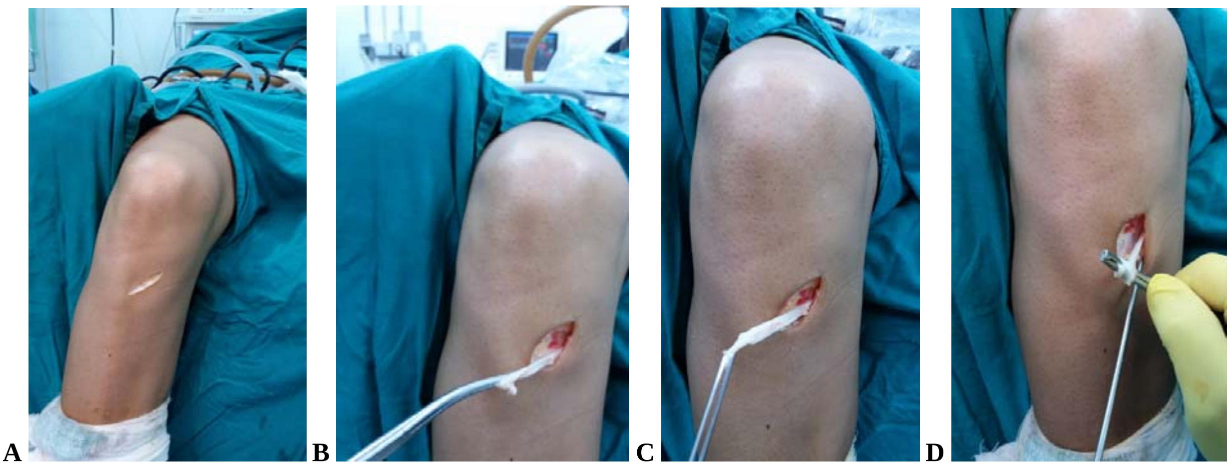

Fig. 1: Graft harvesting: A. Oblique incision for harvest of semitendinosus and gracilis tendons (right knee), B. Gracilis tendon, C. Semitendinosus tendon, D. Introduction of the tendon striper for graft harvesting.

Arthroscopy of the knee was performed to confirm the ACL tear and evaluate other knee pathological conditions.

The femoral tunnels were typically drilled with a freehand technique without a guide through transportal approach using the accessory medial portal. (Fig. 2) With the knee held in 120° of hyperflexion, the arthroscope in the AM portal and after correct identification of the femoral footprints a 2.4 mm guide wire was introduced through the accessory anteromedial (AAM) portal and advanced until it passes the lateral femoral cortex. The tunnel was drilled with a 4.5 mm-diameter cannulated reamer inserted along the guide wire through the AAM portal under arthroscopic visualization through the anteromedial (AM) portal to a depth of 25-30 mm for group (B) and a depth calculated as follows for group (A):

The loop size = the total femoral tunnel – the desired graft in tunnel

The drilling pit = the desired graft length in tunnel + 10 mm for flipping

Fig. 2: Arthroscopic view of the guide wire introduced through the accessory AM portal aiming at the anatomic insertion of ACL in the lateral femoral condyle.

The intra-articular exit of the tibial tunnels should reproduce the footprint of the native ACL. A 2.4 mm guide wire was inserted using the ACL C-guide system. The C-guide was inserted into the joint through the AM arthroscopic portal. The guide wire was drilled from the anteromedial aspect of the proximal tibia through the graft harvest incision and advanced intra-articularly. (Fig. 3) The angle of the C-guide was 55°. The guide wire was overdrilled with a cannulated reamer of the same diameter of the graft.

Fig. 3: Arthroscopic view of tibial tunnel guide wire in the tibial ACL footprint.

The quadrupled semitendinosus and gracilis tendons autograft was passed. After flipping of the endobutton (group A) and tightrope (group B) followed by tensioning of the graft was performed, graft fixation was obtained on the tibial side by interference screw with the knee in 10-15° of flexion.

Finally, arthroscopic inspection and probing of the graft was performed to confirm the tension of the graft, the absence of anterior impingement, and PCL impingement. An intra-articular drain is inserted through anterolateral portal, and another one is inserted through anteromedial portal but passed subcutaneously to graft incision.

The medial fascia over the pes anserinus is closed. Subcutaneous tissue and skin are closed in a standard fashion. Cryotherapy and compression were applied postoperatively.

Immediate Post-operative Care: Patients were allowed to fully weight-bear as tolerated with two crutches for two weeks. Patients were discharged home on the second postoperative day. They were instructed in closed kinetic chain knee exercises, range of motion exercises, and referred to the physiotherapy department for a formal ACL rehabilitation program which began 2-3 weeks after surgery.

Follow Up: The patients were followed up in the orthopaedic outpatient clinic at 2, 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. At the 6 month, 1 and 2 year timeframe we repeated the International Knee Documentation Committee (IKDC) evaluation form, Lysholm score and visual analogue scale (VAS) score.

Results

At two-year follow up, The IKDC score in fixed loop group (A) and adjustable loop group (B) were 93.09 and 92.31 respectively. The Lysholm score in fixed loop group (A) and adjustable loop group (B) were 94.39 and 93.72 respectively. VAS in fixed loop group (A) improved to 3.70, while in adjustable loop group (B) improved to 3.59. The final results are shown in details in table II. Case examples for each group are shown in Fig. 4 and Fig. 5

As regards the complications there have been four cases of superficial infection related to the medial wound of tendon harvest: one in group A and three in group B treated with oral antibiotics with clearance of infection.

There was no reported postoperative deep vein thrombosis in both groups. Moreover, no patient developed graft failure or significant restriction of knee motion to warrant either manipulation under anaesthesia or arthrolysis.

The difference in the results between the two groups was statistically not significant.

Table II: The results of both groups at two-year follow up

	Group A	Group B	P
IKDC			
Range	85-100	85-100	**0.090**
Mean	93.09	92.31	
S.D	4.64	4.48	
Lysholm scale			
Range	85-100	84-100	**0.130**
Mean	94.39	93.72	
S.D	4.28	5.09	
VAS			
Range	3-5	3-5	
Mean	3.70	3.59	**0.130**
S.D	0.82	0.59	

Fig. 4: Postoperative AP and Lateral radiograph of a patient from group A

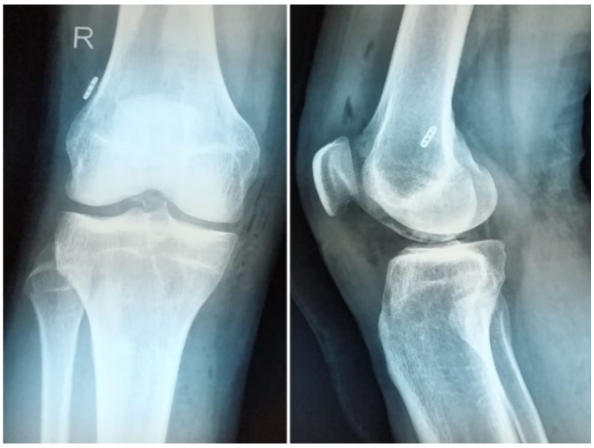

Fig. 5: Postoperative AP and Lateral radiograph of a patient from group B

Discussion

There have been several biomechanical studies comparing the strength and lengthening of fixed versus suspensory loop devices in a laboratory environment. In particular, assessment is made of the lengthening of the suspensory loop when subject to repetitive cyclic loading and also of ultimate failure when subject to load to failure testing. Varying results have been reported.

Biomechanical testing of cortical suspension devices when subjected to simulated high loads experienced during rehabilitation demonstrated significant differences between fixed-loop and adjustable-loop cortical suspension devices. Retensioning did not significantly alter the biomechanical properties of adjustable-loop devices. [17]

Petre et al [18] and Noonan et al [19] also showed on repetitive cyclic testing one of the adjustable loops stretched in excess of 3mm which was beyond the threshold which would be considered a clinical failure. It was noted that fixed-loop devices allowed less cyclic displacement and initial displacement. Adjustable-length loop devices may need to be retensioned after cycling the knee and fixing the tibial side to account for the increased initial displacement seen with these devices

Barrow et al [20] reported the adjustable loop devices lengthening under cyclic loading. This lengthening is partially caused by slippage of the free suture ends into the adjustable loop. This may allow for graft-fixation device lengthening during the early postoperative period. However, they reported this lengthening significantly reduced when the free suture ends were tied.

In a clinical retrospective study, Boyle et al [21] has found that adjustable loop devices lengthen with cyclic loading but confirmed that it was clinically insignificant in postoperative knee stability.

Benjamin et al [22] concluded that fixed-loop devices allowed less cyclic displacement and initial displacement and that adjustable-length loop devices may need to be re-tensioned after cycling the knee and fixing the tibial side to account for the increased initial displacement seen with these devices. Having that being said, it was not encountered by us in the follow up period, any signs of displacement or laxity in the reconstructed knees either radiologically by radiographic assessment or clinically by clinical examination.

Similarly, Aaron et al [23] concluded that the ultimate load of all graft-fixation devices exceeded the forces likely to be experienced in a patient's knee during the early postoperative rehabilitation period. However, the adjustable-length fixation devices experienced a clinically significant increase in loop lengthening during cyclic testing. This lengthening is partially caused by suture slippage into the adjustable-length loop.

Eguchi et al [24] reported a fixed loop suspensory device as having greater statistically significant strength and lower total displacement/ stretching values by comparison to an adjustable loop device.

Perriello et al [25] suggest that the adjustable loop can slip and elongate under load after it has been adjusted to its minimum length.

Fixed and adjustable loop device shown no statistically difference in term of functional outcome at 12 months post operation. [26]

Chang et al [27] reported that the adjustable-loop device is the strongest fixation device at "time zero" in terms of ultimate load to mechanical failure. However, the fixed-loop device demonstrated the least cyclic displacement, which may be more clinically applicable measure of device superiority.

Compared to fixed-loop devices, adjustable-loop devices provide technical advantages, but may be more likely to lengthen during cyclic loading during the early postoperative period. [28, 29]

Smith et al [30] concluded that the adjustable-loop devices behave comparably with fixed ones with regard to biomechanical fixation strength and ultimate knee laxity while also having unique advantages as compared with fixed ones, such as an increased bone-tendon interface and a simplified application.

In a biomechanical study by Cheng et al [31], the fixed loop showed significantly better mechanical properties in failure load and displacement than adjustable loop. [32, 33]

Sheth H et al [34] concluded that arthroscopic ACL reconstruction using fixed loop and adjustable loop suspensory devices are equally effective fixation methods.

Retrospectively, Wise et al [35] found no statistical difference in ACL graft laxity or postoperative functional outcomes between grafts fixed with the adjustable loop or fixed loop button technique.

A biomechanical study performed by Johnson et al [36] found that, even after secondary tensioning, the adjustable loop system was characterized by increased slippage. The increased slippage seen in adjustable loop systems, although biomechanically shown, was not seen in our study. An explanation for this is that the force needed to cause adjustable loop slippage after tensioning actually may be supraphysiologic and therefore does not occur after ACL surgery.

In our present clinical study, we found no difference between the two groups of patients related to operative time (45-60 minutes in group A versus 50-60 minutes in group B) reflecting that both techniques are equivalent regarding simplicity and operative time.

Both groups showed no difference in stability in the last follow up (24-35 months in group A versus 24-38 months in group B). All patients presented to us with stable knees and no one of them complained from instability.

Conclusion

Both adjustable and non-adjustable loop femoral suspensory fixation devices showed no difference in knee stability after anterior cruciate ligament reconstruction.

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