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Objective Outcomes of All-inside Anterior Cruciate Ligament Reconstruction with and Without Internal Suture Augmentation Technique: Randomized Controlled Trial

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Abstract

To report and compare patient outcomes (PROs) (IKDC score, Lysholm Score) and knee laxity using Lachmeter -The digital Rolimeter ® - among patients who underwent hamstrings autograft anterior cruciate ligament reconstruction (ACLR) with and without internal tape augmentation. Randomized trial of 41 patients in which 21 patients underwent all-inside ACLR with internal suture augmentation (Group I, Brace group) and 20 patients underwent all-inside ACLR without internal suture augmentation (Group II, non-brace group). Primary outcomes Lachmeter examinations and PROs were analyzed at 3,6,9 months postoperative. Secondary outcomes were graft failure, synovitis, and infection. Mean follow-up duration was 18 months ± 3.4. Date was expressed as Mean±SD for quantitative parametric data or number and percentage for categorized data. Delta change (dC) principle was used to test the actual mathematical change in the outcomes between 0-9 months and 3-9 months intervals postoperative. Lysholm score at 9-months was significant and better in brace group mean: 94 (92.4-96.5), p<0.005. Postoperative Lachmeter at 3,9 months was significant with less laxity in brace group mean: 1.98 (1.89-2.07), 2.14 (2.06-2.22) p<0.005. dC Lachmeter in both intervals was significant with less laxity in brace group mean: .09 (.06-.11) p<0.001. dC IKDC score was significant in 3-9 months interval mean: .31 (.28-.35) p<0.001. dC Lysholm score was significant in 0-9 months interval mean: .86 (.72-.99) p<0.001. Both scores were better in brace-group. One graft failure was reported in Group II and one case of synovitis in Group I. All-inside ACLR with brace showed better laxity measures and lower failure rate at 9-months postoperative. However, the subjective functional outcomes did not show clear evidence of superiority in the suture tape augmentation group.

Keywords: *Lachmeter, IKDC, Lysholm, all-inside ACLR, internal suture augmentation, randomized controlled trial*

Clinical trial registration number (TRN): NCT04906538 on 05/28/2021

Introduction

Anterior cruciate ligament injury is one of the most common knee injuries, with approximately 250,000 ACL tears occurring in the United States annually (Wang et al., 2018). Revision rate is 1.7% to 7.7% of cases with 35% of first-time graft failures are due to isolated trauma (Adams, Logerstedt, Hunter-Giordano, Axe, & Snyder-Mackler, 2012). In the absence of technical errors and traumatic events; "Biological failure" is a used term to describe such failures because of inadequate graft "ligamentization" during this period while the graft is highly sensitive. (Samitier et al., 2015) The graft usually pass through multiple histological stages; necrosis, revasculariza-

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tion, cellular repopulation and proliferation and remodeling (Ménétrey, Duthon, Laumonier, & Fritschy, 2008). Finally, collagen remodeling continues to happen during the first year after surgery by changing the non-reducible/ reducible crosslink ratio in collagen fibrils (Marumo, Saito, Yamagishi, & Fujii, 2005). Therefore, protection of the graft during these phases in a controlled manner to apply within limit mechanical loads over the graft could offer lower chances for mechanical and biological failure. This could act as "safety belt" for the graft and confirm the theory of internal suture augmentation (van Eck, Limpisvasti, & ElAttrache, 2018).

In 2006, Lubowitz described the all-inside technique using a dual retro-cutter (Arthrex, Naples, FL) that after its intra-articular assembly allows for both anatomical antegrade and retrograde femoral and tibial tunnels drilling respectively (Lubowitz, 2006). Recently, (FlipCutter; Arthrex) simplified the inside out tunnel drilling (Lubowitz, Amhad, & Anderson, 2011).

Suture tape – a braided ultra-high-molecular-weight polyethylene material – reinforcement has been described in effort to provide biomechanical support during the graft healing phases (Parkes et al., 2021). This suture tape was used successfully to augment Brostrom repair, and posteromedial corner repair (Viens, Wijdicks, Campbell, LaPrade, & Clanton, 2014) (Lubowitz, MacKay, & Gilmer, 2014). Samuel Bachmaier et al. concluded in his study testing biomechanical full construct hamstrings tendons model with internal suture augmentation that the reinforcement with suture tape increases the dynamic stiffness and ultimate load failure and decreases the dynamic elongation in the augmented sample (Bachmaier, Smith, Bley, & Wijdicks, 2018).

Arthrometric testing represents a useful objective tool that used ACL examination. The KT-1000 and KT-2000 (MEDmetric Corp, San Diego, Calif., USA) have been developed to provide acceptably accurate and reproducible laxity measurements (Daniel et al., 1985). Furthermore, the Rolimeter (Aircast, Europe) is a simple, new device that provides a comparable measurement to KT- devices (Ganko, Engebretsen, & Ozer, 2000). Lachmeter - The digital Rolimeter® is the selected device in our study that follows all the principles, validation, and technique of the Rolimeter, while providing its measured values of laxity on a digital screen rather than a metered scale as in the original Rolimeter.

The purpose of this study was

1. To report, compare and corelate the patient reported outcomes (PRO) (IKDC score, Lysholm Score) and range of motion (ROM) among patients following hamstring autograft ACLR with and without independent suture tape reinforcement against objective laxity test using Lachmeter.

2. Rate of complications and reoperations.

We hypothesize that Internal suture augmentation technique decreases post-operative graft failure rate, improves the knee stability and the patients reported functional outcomes of the knee.

Materials and methods

Study design

This randomized control trial was conducted in Ain Shams University Hospitals, following the Ethical Committee of Orthopedic Surgery Department approval, reference number: FMASU MD 310 2018 and was registered in ClinicalTrial.gov, Identifier: NCT04906538 on May 28, 2021. All surgeries were operated by two senior surgeons (Sobhy. M and Khater. A). Pre-operative and post-operative examinations, evaluations, and subjective assessment by Lachmeter were performed by Ramadan A and Haroun Y. CONSORT flow diagram was used throughout the study steps.

Study population

October 2018 until June 2020, 41 patients with torn ACL met the inclusion criteria. 21 of patients underwent all-inside ACL reconstruction with internal suture augmentation technique (Group I) and the other 20 patients underwent all-inside ACL reconstruction without internal suture augmentation technique (Group II).

- Inclusion criteria:

Age 20-35 years.

Subjects diagnosed as ACL tear according to:

(a) History of knee trauma

(b) Clinical examination (ant. Drawer test, Lachman test and pivot shift test).

(c) Radiological evidence of ACL tear by MRI.

- Exclusion criteria:

(1) Other intra or extra articular knee injuries.

(2) Previous ACL surgery on the affected knee.

(3) Bilateral ACL injuries.

(4) Significant Articular surface injury.

(5) Patients with malalignment (Genu varum, Genu valgum and Genu recurvatum).

(6) Neuromuscular disorders.

Study outcomes

Primary study outcomes: Lachmeter laxity test, IKDC score and Lysholm score. Supported by clinical examinations (pre and postoperative anterior Drawer test, pre and postoperative Lachman test, pivot shift test and ROM). These outcomes and examinations were tested for each patient preoperative, immediate postoperative and 3,6,9 months postoperative.

As secondary outcomes, we recorded any case of failure, infection, synovitis or limited ROM.

Study intervention (Surgical technique)

All the patients included in the study underwent primary ACLR using all-inside technique with quadruple semitendinosus autograft employing the GraftLink® (Arthrex, Naples, FL) with suspensory fixation Tightrope®, (Arthrex, Naples, FL) on the femoral side. The graft is pretensioned for 15 minutes at approximately 70 N to eliminate creep. Group 1 grafts were augmented by FiberTape® (Arthrex, Naples, FL) suture – ultra-high molecular weight polyethylene core with a braided polyester jacket which passed through the femoral Tightrope® loop while the fiber tape tibial free ends are kept free in the opposite direction.

The graft's tibial end is sutured with no. 2 FiberWire sutures (Arthrex) while FiberTape® suture is outside the construct to avoid sutures loop incorporation. The femoral tunnel was created by antegrade drilling using accessory antromedial portal for at least 20-25 mm intraosseous depth. The tibial socket is created in retrograde fashion utilizing a FlipCutter® for an intraosseous depth of at least 25 mm to keep the medial tibial cortex intact. Then, the graft is passed inside the joint from the accessory antromedial portal and the femoral Tight Rope® is introduced inside the knee until it flips on the lateral femoral cortex.

The shortening sutures are pulled in an alternating fash-

ion to hoist the graft in the femoral tunnel for 15 mm. Special mark is added to the graft using no. 2/0 Vicryl suture (Ethicon Inc.) 15 mm from both ends to ease graft manipulation inside the knee Figure 1.

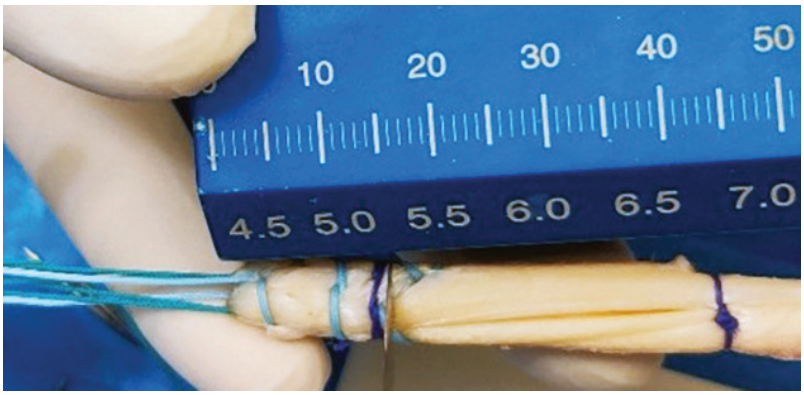

FIGURE 1. Special mark using 2/0 Vicryl suture 15 mm from each graft's side to facilitate intra-articular adjustmen

The graft's and FiberTape sutures are passed and pulled through tibial socket using no. 2 Ethibond nonabsorbable sutures (Ethicon Inc., Somerville, New Jersey, USA), as a shuttle suture, and then secured over Attachable Button System (ABS) (Arthrex, Naples, FL) Figure 2. Multiple knee cycling is routinely performed to add more tension to the construct.

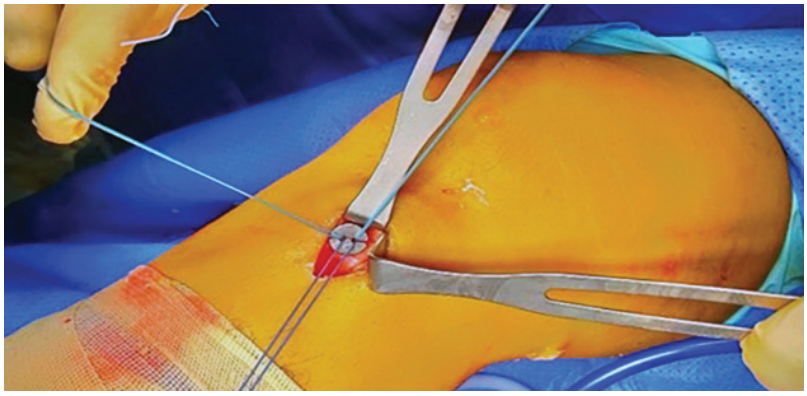

FIGURE 2. Attachable Button System (ABS) (Arthrex, Naples, FL) is fixed on the intact medial tibial cortex. The graft sutures free ends and the FiberTape® are passed through ABS button to be tightened independently.

Final sutures fixation steps are performed in the following sequence: Firstly, the free ends of the FiberTape® are sutured manually whilst the knee is in full extension. Secondly, the free ends of graft's sutures are fixed whilst the knee in 30-degree flexion. Finally, more graft tension is achieved through the femoral Tightrope® and all the construct is checked arthroscopically ensuring that the FiberTape® is slightly more lax than the graft after final tensioning figure 3. This is a modification of the original technique where the fiber tape is fixed by knotless anchor. Tensioning of the graft depends on tight manual fixation of both graft's sutures and FiberTape® free ends over ABS button on tibial side by the same surgeon. More tensioning is achieved by final femoral Tightrope® sutures shortening.

Postoperatively, full range of motion is allowed with full weight-bearing as tolerated once the patient demonstrates a well-functioning quadriceps muscle and good leg control. Closed chain strengthening exercise is emphasized and return to full activity is allowed between 6 to 9 months postoperatively.

Randomization and power analysis

Power analysis was performed using MedCalc1 Statistics Software v.15.8 (bvba, Ostend, Belgium) with a 20 subjects sample size for each group. 44 patients received for intervention and were classified by computer-generated randomization into 2 groups using Random Allocation Software V.4.5 (Asfahan, IR): (Group I) "Brace group" and (Group II) "non-Brace group". Unfortunately, 2 patients were lost during their early follow up due to COVID- 19 outbreak.

Statistical analysis

Collected data was stored in Microsoft Excel (2010; Microsoft Corp.), and analyzed using IBM® SPSS® Statistics version 23. Data was subdivided to parametric and non-parametric data using Kolgomorov and Shapiro tests.

Date was expressed as Mean±SD for quantitative measures (Lachmeter, IKDC score, Lysholm score, ROM, demographic data) and in both number and percentage for categorized data (pre-pivot test, pre-Lachman test).

The following tests were done:

1. Comparison between two independent mean groups for parametric data using Student t test.
2. Comparison between two independent groups for non-parametric data using Mann-Whitney U test.
3. Chi-square test to study the association between each 2 variables or comparison between 2 independent groups as regards the categorized data.

The degree of change during follow-up variable (delta change or dC) reflects the actual mathematical difference that

FIGURE 3. Intra-operative arthroscopic view from viewing anterolateral portal showing tightened graft and a slightly lax fiber tape while the knee in 300 flexion..

happened during the follow-up period (0 – 9 months postoperative) and can be calculated for each patient, from which, the mean delta change can be compared with other group or correlate with other variables. It is defined as follow: Delta change (dC) = (Post-Pre)/Pre. The probability of error at 0.05 was considered significant.

Results

The mean duration of follow up in our study was 18±3.4 months (range: 12-24 months). All patients were males, mean age of 29.9±5.1 years (range: 22-35 years) for Group I and the mean age of 26.7±4.09 years (range: 22-35 years) for group II. There was no significant difference between both groups regarding demographic data (age, side of injury, time since injury) Table 1 and initial manual assessment tests (pre-pivot test, pre-lachman test) Table 1.

Patient reported outcomes PROs (IKDC score, Lysholm score) and the objective knee laxity measurement by Lachmeter were reported at preoperative time, immediate postoperative and 3,9 months postoperative. There was no significant difference between the two groups at initial assessment (Lachmeter for non-injured knee and Preoperative IKDC) (P values are .87 and .819 respectively). As a reference value, Lachmeter test was done for the injured knee immediately postoperative and labeled as Lachmeter 0, which showed no significant difference between the two groups (P value .5). At 3-month postoperative assessment, laxity assessment showed significant difference between the two groups (P value .000) to be lower in Brace group, but it was insignificant regarding IKDC and Lysholm scores (P values .696 and .171 respectively). At 9-months postoperative assessment, Lysholm score showed significant difference between the two groups (higher in Brace group) and Lachmeter examination (lower in Brace group) (P values .000 and .000 respectively). However, it was not significant regarding IKDC score (P value .239) Table 2.

Table 1. Demographic characteristics of included patients and initial manual assessment

	Brace group	Non-brace group	P value
N	21	20	------
Age (years)[a]	29.9 ± 5.1(range: 22-35)	26.7 ± 4.09 (range: 22-35)	0.477
Side of injury	Right (18), Left (3)	Right (9), Left (11)	0.516
Time since injury (months)a	8.57 ± 9.91 (range: .6-36)	8.94 ± 4.91 (range: 2-15)	0.500
Pre-pivot test			
Grade 1 [b]	2 (10%)	3 (15%)	0.010 *
Grade 2 [b]	12 (57%)	11 (55%)	
Grade 3 [b]	7 (33%)	6 (30%)	
Grade 4 [b]	0 (0%)	0 (0%)	
Pre-Lachman test			
Grade 1[b]	1 (5%)	1(5%)	0.100
Grade 2[b]	13 (62%)	12(60%)	
Grade 3[b]	7 (33%)	7 (35%)	
Grade 4[b]	0 (0%)	0 (0%)	

[a] Values are expressed in terms of (Mean ± SD (Range)); [b] values are expressed in terms of (Count(%)); *Significant at p<0.05 level.

Range of motion (ROM) was measured throughout the study at preoperative time and 3,9 months postoperative. Normal ROM is considered from 0 (full extension) to 135 knee flexion. There is no significant difference between the two groups in pre-ROM, 3,9 months postoperative (P values .851,.431,.133 respectively) (Table 3).

Delta change or (dC) was tested extensively throughout the three main outcomes in this study (Lachmeter, IKDC score,

Table 2. Lachmeter Test and PROs (IKDC, Lysholm)

	Brace group	Non-brace group	P value
Lachmeter test			
Normal side Lachmeter	1.98 (1.87-2.08)	2.09 (1.97-2.21)	0.870
Injured side Lachmeter	5.55 (5.08-6.02)	6.9 (6.1.3-7.66)	0.001*
Lachmeter 0	1.96 (1.88-2.04)	2.13 (2.02-2.25)	0.560
Lachmeter 3	1.98 (1.89-2.07)	2.3 (2.19-2.4)	0.000*
Lachmeter 9	2.14 (2.06-2.22)	2.81 (2.52-3.09)	0.000*
IKDC score			
Pre-operative	49.7 (47.3- 52)	50.5 (47.9-53.2)	0.819
IKDC 3	68.9 (67.3-70.4)	68 (65.3-70.7)	0.696
IKDC 9	90.6 (89.6-91.5)	88.2 (85.3-91)	0.239
Lysholm score			
Pre-operative	51.3 (48.6-53.9)	60.9 (58.1-63.7)	0.000*
Lysholm 3	74.5 (71.5-77.5)	70.6 (68-73.2)	0.171
Lysholm 9	94 (92.4-96.5)	89 (85.7-92.2)	0.000*

Values are expressed in terms of (Mean (95% CI)), *Significant at p<0.05 level.

Lysholm score). There is no significant difference between the two groups regarding dC IKDC 0-9 months and dC Lysholm 3-9 months (P values .819, .919 respectively). However, there was significant difference in the following parameters: dC IKDC 3-9 months, dC Lysholm 0-9, dC Lachmeter 0 – 9 months and dC Lachmeter 3 - 9 months (P values .001, .001, .001, .000, .001 respectively) Table 3.

Finally, the only reported failed ACLR case was one patient in the non-Brace group. The reported traumatic event was knee twisting injury inside home at 9 months postoperative.

Table 3: Range of Motion (ROM) Assessment and Delta Change (dC) Assessment

	Brace group	Non-brace group	P value
Range of motion (ROM)			
Pre-operative ROM	131 (126.2-135.7)	133 (131.6-135)	0.851
ROM 3	100.2 (97.3-103.1)	102 (99-104)	0.431
ROM 9	129.7 (127.2-132.2)	126.9 (124.3-129.5)	0.133
Delta change (dC) assessment			
dC Lachmeter			
0 -9 months (injured side)	0.09 (0.06-0.11)	0.32 (0.18-0.46)	0.000*
3 – 9 months (injured side)	0.09 (0.06-0.11)	0.32 (0.18-0.46)	0.001*
dC IKDC score			
0-9 months	0.84 (0.75-0.94)	0.55 (0.47-0.64)	0.819
3-9 months	0.31 (0.28-0.35)	0.22 (0.18-0.26)	0.001*
dC Lysholm score			
0-9 months	0.86 (0.72-0.99)	0.46 (0.38-0.54)	0.001*
3-9 months	0.26 (0.22-0.31)	0.26 (0.20-0.33)	0.919

Values are expressed in terms of (Mean (95% CI)), *Significant at p<0.05 level.

This failure was confirmed by clinical examination and MRI examination. Revision surgery was performed 3 months later, and the failed graft was elongated and lax throughout its intra-articular course. Another case in non-Brace group suffered from arthrofibrosis 2 months postoperative and improved by arthroscopic arthrolysis. Synovitis occurred in two cases from Brace group at 3, 5 months postoperative which resolved without further surgical intervention. The risk of low-grade infection was excluded by serial normal ESR, CRP and WBCs levels. Only one case in non-brace group was a professional player who returned to sport after one year.

Discussion

All-inside ACLR technique is a well-established technique with several studies to test and review its principles and outcomes (Cerulli, Zamarra, Vercillo, & Pelosi, 2011; Blackman & Stuart, 2014; Connaughton, Geeslin, & Uggen, 2017). To our knowledge, no published study used an objective tool to judge the results and compare them with functional outcome.

The used graft tensioning sequence depends on the fact that knee joint space experienced consistent length decreases of 1 mm at 30o flexion (Li, Defrate, Rubash, & Gill, 2005; Bachmaier et al., 2018).Therefore, fixing the graft in 30o flex-

ion will make it shorter by 1 mm than the brace that is fixed in full extension. This is ideal to prevent brace stress shielding and promotes graft ligamentization. This is aided by the fact that graft and suture tape are fixed "independently" as each has its own knot over ABS button. Final tensioning from femoral adjusts any loosening after manual tibial fixation and to standardize construct tension (Smith, Bradley, Konicek, Bley, & Wijdicks, 2020). This could be an alternative sutures fixation technique that depends on innate knee kinematics instead of using hemostat as Patrick et al described (Smith & Bley, 2016) to prevent brace- graft stress shielding. The demographic data in both groups showed no significant difference and this omit any influence of these factors on the results.

The core value in this study is an objective measurement of knee laxity using the Lachmeter whose higher value (higher mean) indicate more laxity. The used validated scores scale from 0 to 100, where score 100 is the best outcome in both scales. Functional scores were not conclusive regarding difference; as only Lysholm score 9 months postoperative was significant and its mean was higher (better) in brace group. Additionally, 3, 9 months postoperative Lachmeter assessments showed significant difference between groups with lower means (less laxity) in brace group. These functional scores are consistent with Parkes CW et al. results (Parkes et al., 2021).

Do these reported values change enough to make a real difference? In functional scores assessment; the higher the dC the better outcome at the end point. On the other hand, in Lachmeter examination the lower the dC the better outcome and less laxity at the end point. This is judged via means values across the two groups. IKDC score showed significant change in 3-9 months interval. Whereas Lysholm score was significant in 0-9 months interval. Both have higher mean scores in brace group. Furthermore. Lachmeter examination dC was significant in both tested intervals (0-9 months, 3-9 months postoperative) with lower mean dC in brace group (less laxity) as shown in Table 3. This last finding could potentiate the principle "safety belt" as suture tape augmentation ACLRs statistically showed less laxity at 9- month postoperative.

Finally, the reported knee effusion in brace group may raise the question about suture tape material biocompatibility. However, this case was treated conservatively and did not need any further intervention. On the other hand, the only failed case that was in non-brace group, occurred at 9 months postoperative, have a great influence in understanding the importance of bracing the vulnerable graft during the ligamentization period. This is supported by the fact that without technical error, biological failure is the chief type of failure in early ACLR operations (George, Dunn, & Spindler, 2006).

Limitations

The operated cases were middle aged persons without professional sports involvement. Thus, return to sport entity was not well presented. The correlation between detailed operative data such as graft thickness and type was not conducted and compared .

Conclusion

All-inside ACLR technique with hamstrings autograft and independent suture tape augmentation showed better outcomes regarding objective knee laxity testing at 9 months postoperative and lower failure rate when compared to the same technique without independent suture tape augmentation. However, the subjective functional outcomes show no suture tape augmentation superiority.

Recommended further studies

This study protocol and methodology could be more informative if conducted over larger study group of professional athletes to find out the actual efficacy of suture tape augmentation technique to protect ACL grafts.

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Conflict of Interest
The author declares that there is no conflict of interest.

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