WITHDRAWN: Outcome of Anterior Curciate Ligament Reconstruction with a Large-size Graft versus an Extraarticular Tenodesis; A Comparative study

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Research Article

Keywords: large sized ACL graft diameter, combination of anterir cruciate ligamen reconstruction with extra-articular Tenodesis, modified Lemaire, graft failure, rotatory instability after ACL-R, pivot shift test

Posted Date: June 14th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1611240/v1

EDITORIAL NOTE:

The full text of this preprint has been withdrawn by the authors while they make corrections to the work. Therefore, the authors do not wish this work to be cited as a reference. Questions should be directed to the corresponding author.

Abstract

Introduction: Large number of patients after Anterior Cruciate Ligament (ACL) reconstruction (R) complain of instability, inability to return to the previous level of sports activity and develop ACL graft failure. There are two augmentations to ACL-R to increasec the stability of knee. Those augmentations either a large-size ACL-graft or combination with extraarticular tenodesis (LET). .

Patients and Methods: A Prospective Randomized Comparative study included 100 consecutive patients, who underwent ACL-R with Hamstring Tendon Graft. The patients were allocated into two groups (Group A and B) with Randomization; group A received ACL-R with a large ACL-graft diameter (Triple graft) and group B received ACL-R with a double graft combined with lateral extraarticular tenodesis (Modified Lamaire). Each group had fifty patients. Follow-up was for 2 years. They were examined for graft failure, rotatory instability with the pivot shift test and the outcomes were measured with the international knee documentation committee‘s (IKDC) both subjective and objective scores.

Results: In group A, graft failure occurred in two (4.1%) patients, the pivot shift test was positive in three (6.5%) patients, the subjective IKDC score was 90.94 points, and the objective IKDC score was normal or nearly normal in 43 (93.4%) patients. In group B, graft failure occurred in one (2.1%) patient, the pivot shift test was positive in one (2.1%) patient, the subjective IKDC score was 91.9 points, and the objective IKDC score was normal or nearly normal in 44 (95.6%) patients.

Conclusion: Both large graft-diameter and combination with extra-articular tenodesis decrease ACL-graft failure rates, postoperative rotatory instability, and improve clinical outcome. However, the combination of anterior curciate ligament reconstruction with extra-articular tenodesis was more effective than large-sized grafts for curciate ligament reconstruction.

Level of evidence: Level 1; Randomized Comparative study.

Introduction

In recent years, considerable attention has been given to anterolateral rotatory instability of the knee. This complex rotatory instability must be addressed at the time of anterior cruciate ligament reconstruction (ACL-R) surgery to improve patient outcome, minimize recurrence, and optimize return to pre-injury levels of sports. 18–40% of patients after ACL-R experience recurrent subjective instability or an inability to return to their previous level of sports participation [1, 2]. Rotatory instability is one of the most important determinants of whether a patient can return to sports after an ACL-R [3]. Patients with poor rotational control after ACL-R may be predisposed to graft failure [4].

The dynamic laxity of the knee, which is the tibial rotation during a giving way symptom, is assessed by the pivot shift test [5]. The test is graded into grade I, II and III levels based on the severity of anterolateral rotatory instability [6, 7]. Recent evidence suggests that, the pivot shift is multifactorial and can be detected with concomitant injury to secondary stabilizers or with predisposing anatomical factors [8]. The

presence of positive pivot shift postoperatively is associated with poorer outcomes after ACL reconstruction [9].

The pivot shift test is a subjective one and has high intra-observer and inter-observer variability [10]. To overcome the problem of the accuracy of pivot shift, novel devices have been developed, that quantitatively measure pivot shift, such as navigation systems [11], electromagnetic sensors [3], inertial sensors [12] and image analysis systems [13]. However, none of these methods has widespread acceptance among surgeons, and many of these devices remain examiner-dependent. The pivot-shift test remains the gold standard and is the most popular test. To improve the accuracy and reproducibility of the pivot shift test, standardizing the pivot shift test technique as explained by Hoshino [14]. This explanation provides a more consistent quantitative evaluation.

Reduction of rotatory instability and failure rate can also be done with double-bundle reconstruction, which reproduces the native ACL biomechanics [15, 16]. However, the double-bundle ACL surgical technique is more demanding and may be associated with an increased risk of intra-operative complications [17].

Conceivably, a large-diameter single-bundle graft may work as a double-bundle graft because of a larger contact area between the graft and the bone tunnel wall and may restore rotatory instability. Large diameter (Triple-ACL graft) has also demonstrated to lower ACL-failure rate [18, 19].

The rotational instability is also reduced when a single-bundle ACL-R is combined with lateral extra-articular tenodesis (LET) [4, 20].

Zaffagnini et al. [21] compared the outcome of ACL-R in the double bundle technique and single bundle ACL-R combined with LET and found that the double-bundle was superior to the combination with LET in terms of rotational stability and return to sport.

The purpose of this prospective study was to compare the rotatory instability, failure rate and clinical outcome of two ACL-R techniques with hamstring tendons: one with a single intra-articular bundle, large diameter triple-graft (6 strands) and second a single bundle double-graft (4 strands) combined with LET.

The hypothesis was ACL-R technique combined with LET resulted in decreased rotatory laxity, failure rate and improvement of clinical outcome more than large-size graft ACL-R.

Patients And Methods

A prospective randomized comparative study took place from March 2016 to March 2020. One hundred unilateral consecutive patients with an ACL tear and grade II pivot shift tests or more, were primarily operated on. To avoid bias, expertise based concealed randomization was employed to allocate the patients into two groups; A and B. ACL-R was done. They were operated on with Semitendonosus-Gracilis (STG) tendons, either a triple STG (6 strands) graft alone in group A and a double STG (4 strands) graft combined with LET in group B.

Each group has fifty patients. Follow-up was for a minimum of 24 (range, 24-31) months. From a statistical point of view, the composition of the two groups preoperatively in terms of mean age, sex and BMI was highly homogenous (Table 1). Two patients from group A and three patients from group B were lost to follow up. Eventually, 95 patients (95%) were available for follow- up (Table 1).

(Table 1) Patient demographic data (N. 95; group A 48 and group B 47 patients).

	Group A	Group B
Mean age at surgery (years)	27 (19 to 43)	28 (20 to 42)
Male/female	41/7	39/8
BMI, kg/m2, n (%)		
Normal (18.5-25)	32	33
Overweight (25-30)	14	13
Obese (>30)	2	1
Side (Right/Left)	30/18	32/15
Mechanism of injury		
Sport injury	19	22
Social	24	18
Motor car accident	5	7
Interval between injury and surgery (months)	7 (2 to 12)	9 (2 to 19)
Meniscal surgery		
Repair No (%)	4 (8.3%)	5 (10.6%)
Menisectomy No (%)	22 (45.8 %)	24 (53.2 %)

(BMI : Body mass index)

Table 2: Comparison of group A (N 48) and B (N 47) of ACL graft failure, comparison of group A (N 46) and B (N 46) after exclusion of graft failure cases with regards to pivot shift test, subjective and objective IKDC score, 2 years postoperatively.

	Group A	Group B	*P* value
ACL failure (%)	2/48 (4.1%)	1/47 (2.1%)	
Pivot shift test, +/Total (%)	3/46 (6.5%)	1/46 (2.1%)	0.311
Subjective IKDC score	90.94 (Range, 56.3 - 100)	91.9 (Range, 50.5 - 100)	0.368
Objective IKDC score	A B C D 30 13 3 0	A B C D 28 16 2 0	

The local ethics committee approved the study. Informed consent was signed by every patient before participation.

Patients were recruited from the orthopaedic sports medicine clinic, examined clinically, and investigated with MRI. The clinicians screened for potential participants and provided information about the research study and its importance.

Patients were examined four times before the operation. Initially, at the first presentation in the outpatient clinic, second time at admission to the orthopaedic department. The third time, at operation before anaesthesia and the fourth time after anaesthesia. All examinations confirm high instability; with pivot shift II or more. As the pivot shift test depends on the skill and experience of the examiner, there was an agreement among physicians about the pivot shift test and its grading according to Jakop [6, 7].

Inclusion criteria

1. ACL deficient knee was clinically manifested by positive anterior drawer, Lachmann, and positive pivot shift tests in comparison to the contralateral side, and was confirmed by MRI.
2. A skeletally mature patient.
3. A positive pivot shift of at least Grade II is required.
4. Associated lesions; meniscal injuries, or injury of medial collateral ligament (MCL) ≤ grade I.
5. 18-45 years of age.

Exclusion criteria

1. Patients who have been polytraumatized or have multiple ligament injuries
2. Revisions or ACL tear in the opposite knee
3. Generalized laxity.
4. Symptomatic articular cartilage defect requiring treatment; Outerbridge > grade II.
5. More than three degrees of varus or valgus mal-alignment

6. Intraoperative complications associated with failure of the graft, such as femoral tunnel blow-out or malposition
7. Unable to provide informed consent.

Follow-up examinations were scheduled to be in 2 weeks, 6 weeks, 6 months, 1 and 2 years, postoperatively. Patients at last follow-up; in 2 years, were invited for examination in the outpatient clinic three times by the same experienced physician from the study team, to overcome both intra- and inter-observer variability. The discrimination of the dynamic grades of pivot shift test was not performed. No grading was done, to reduce the subjectivity of the test by making its interpretation as simple as possible. Grading needs more refinement in the examination and may need anesthesia [7]. In the last follow-up, patients fill the translated form of IKDC score [22] (Table 2). The clinician was blinded from patient data during follow up and coverage of the knee with elastic bandage for all patients, to hide individual groups; A and B.

Surgical technique

Patients underwent an anatomic ACL-R. To limit the variability, all ACL-Rs were performed in a standardized fashion by the same surgical staff. The surgeon randomly performed either ACL-R alone or ACL-R combined with LET in 1:1 ratio.

The hamstring autograft was harvested following the traditional technique. The graft was measured, and bony tunnels were drilled. An anatomical reconstruction technique was used in all cases.

In group A, the surgeon used a triple STG hamstring (six-strand) tendon graft. Intra-operative measurements of the fashioned six-strand hamstring graft were performed using sizing tubes, calibrated to 0.5 mm (**Fig. 1, 2**). The graft diameters were measured and found to be in the range of 8.5-11.0 mm. The transportal technique was used to drill the femoral tunnel. Femoral and tibial fixations were performed with bio-absorbable interference screws (Smith & Nephew Endoscopy).

In group B, the surgeon used a double STG hamstring (four-strand) tendon graft. The graft diameters were measured and found to be in the range of 7.5-10.0 mm. Femoral and tibial fixations were also performed by bio-absorbable interference screws (Smith & Nephew Endoscopy). Following this, LET was performed in a standardized fashion as described in the modified Lemaire technique [23] (**Fig. 3, 4**).

Postoperative rehabilitation

All patients, regardless of the group allocation, underwent identical postoperative rehabilitation. Attention was given to early range of motion and weight-bearing as tolerated, unless a meniscal repair dictated otherwise. A hinged knee brace was used for the first 6 weeks.

Physical rehabilitation was carried out as follows:

0–6 weeks: As tolerated, progressive Continuous Passive Motion (CPM) with a machine, 0-90 range of motion exercises, swelling control, quadriceps activation, muscle stretching and strengthening.

6–12 weeks: Progressive full range of motion exercises, muscle strength and proprioception.

3–6 months: Flexibility and sport specific muscle strengthening.

6–9 months: Sport specific training.

9 months +: Return to sport if meeting functional requirements.

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Outcome measures

The primary outcome measure was a graft failure, identified as a symptomatic instability with a positive pivot shift test and confirmed with MRI.

S*econdary outcome measures* were the pivot shift test, and subjective and objective International Knee Documentation Committee (IKDC) [24] scores.

Statistical analysis.

The data was analyzed using SPSS software (Version 25; SPSS Inc, Chicago, Illinois, USA). Statistical analysis was performed by an independent statistician. Descriptive statistics for variables such as age, body mass index (BMI), sex, concomitant knee pathologies, failure rate, and graft size were generated. For normally distributed data, the mean was calculated for the IKDC score, age, duration of symptoms and follow-up. Paired student t-tests were used to compare the improvement of the items of IKDC score between the two groups. A *p*-value of less than or equal to 0.05 was considered statistically significant.

Results

In group A, during follow-up examination, graft failure was perceived in two (4.1%) cases. One case occurred without trauma at 6 weeks postoperatively. The second case occurred two years ago, just before the follow-up examination after a new significant trauma. The graft diameters for those two failure cases were 8.5 mm and 9 mm. While in group B, graft failure was perceived in one (2.1%) patient at 23 months postoperatively with new significant trauma (Table 2).

Those cases of graft failure were identified clinically and confirmed with MRI. They were considered a failure of treatment and were excluded from subsequent follow-up examinations. The three cases of graft failure underwent ACL-revision combined with LET (Modified Lemaire). The two cases in group A, received ACL-revision combined with ipsilateral LET. The case, in group B, received ACL-revision combined with graft for LET from the contralateral side with the free ends fixed with interference screws.

Regarding the pivot shift test, it was performed on all patients by a single senior clinician at follow-up examinations (3 times for each patient in the last follow-up). It was positive in four patients after two yetars (Table 2 and Fig. 5). Those cases were confirmed to be positive and low grade. However, grading was not done.

All patients reported a satisfactory feeling of stability in the operated knee, despite the result of the pivot shift test detected at physical examination. The four cases of positive pivot shift test underwent MRI, which demonstrated an intact ACL-graft.

At a two-year follow-up examination, subjective and objective IKDC scores were recorded (Table 2). The time to return to sports for sports-player patients was scheduled to be 9 months after surgery. After this period, all sports players (No 18 in group A and No 20 in group B) returned to their sport. Graft failure cases were outside the sports player group.

Regarding the age correlation, there was a statistically significant correlation between age and subjective IKDC scores (Pearson correlation coefficient r was − .825, *p* value was < 0.00001 for group A and − 0.6651, *p* value was < 0.00001 for group B, respectively) (Table 3).

Table 3
Age groups of the patients and the corresponding mean subjective IKDC score. (N 46 for group A and B, each) together with the differences in IKDC scores for the same age group.

Age group	N. in group A	Subjective IKDC for A	N. in group B	Subjective IKDC for B	*P* value
< 20	2	100	0		-
20–25	15	95.2	21	96.1	0.244550
26–30	13	92.2	12	94.2	0.134484
31–35	12	84.7	8	83.6	0.323564
36–40	2	82.5	4	81.2	0.262445
40 <	2	57.1	1	58.6	0.213952

Regarding the correlation of the body mass index (BMI) to the subjective IKDC scores, there was a statistically no significant correlation between BMI and subjective IKDC scores (Pearson correlation coefficient r was 0.1666, *p* value was 0.257742 for group A and − 0.1027, 0.495094 for group B, respectively) (Table 4).

Table 4
The BMI groups and the corresponding subjective IKDC scores for group A and group B (each N 46) together with the differences in IKDC scores for the same BMI group.

BMI	group A	IKDC score group A	group B	IKDC score group B	*P* value
Underweight	0	0	0	0	0
Normal BMI	31	89.6	32	92.1	0.25755
Overweight	13	93.3	13	91.1	0.51343
Obese	2	91.9	1	92.7	0.50173

Regarding gender correlation, there was no correlation between gender and the mean subjective IKDC scores for both groups A and B (Table 5).

Table 5
The gender and the mean subjective IKDC scores for group A and B (N 46 each) together with the differences in IKDC scores between the two groups.

Sex	Group A	IKDC score group A	Group B	IKDC score group B	*P* value
Male	39	90.9	38	91.8	0.29185
Female	7	88.9	8	90.7	0.33337
P value		0.246277		0.357649	

According to the subjective IKDC grading system originally utilized by Haas et al.[25] and later utilized by Griffith et al.[26], subjective IKDC scores were classified (Table 6). Higher IKDC scores in the current study (58 patients; 63%) with excellent IKDC scores were associated with a return to the previous level of sport participation when compared to lower scores.

Table 6
Classification of subjective IKDC score in each group (N 46).

	Group A	Group B	*P* value
Excellent IKDC (score, 90–100)	27	31	0.371619
Good IKDC (score, 80–90)	16	13	0.779101
Fair IKDC (score, 70–80)	1	0	-
Poor IKDC (score, < 70)	2	2	0.630281

Clinically, the Lachman test was judged as negative in 46 patients in each group. All patients' final range of motion was complete.

Postoperative radiographic evaluation revealed no errors in tibial and femoral tunnel placement, and there were no differences in tunnel enlargement. Moreover, there were no differences regarding arthritic degenerative changes related to surgery between the two groups, although at a relatively short term follow-up.

No hardware removal was necessary in any of the patients in either group. In both groups, no complications due to the surgical procedure were observed.

Discussion

An important finding of this study was that both techniques, large-size graft diameter and combination with extra-articular tenodesis, decreased the failure rate of ACL-R, rotatory laxity, and improvement of clinical outcome. However, the ACLR-LET combination group was superior to the large ACL-graft diameter group. The hypothesis was confirmed. This may be explained by the fact that, in the knee in the ACLR-LET combination group, there are two points of fixations, but in the ACL-R with large graft diameter group, there is only one point of fixation.

In regard to group A, with an 8.5–11 mm graft diameter, graft failure occurred in two (4.1%) of 48 cases. One case occurred without trauma at 6 weeks, which may be related to the faulty technique or failed graft healing. The second case occurred two years postoperatively, just before a follow-up examination with new significant trauma. Superior results were noted by Tang et al. [18] in their retrospective study on 394 patients. Graft failure was zero if the graft diameter was greater than 8 mm. The Swedish group [19] reported a decreased likelihood of graft failure after ACL-R in 560 cases with an increment in the hamstring autograft diameter between 7.0 and 10.0 mm. For every increment of 0.5 mm in the hamstring graft diameter, the likelihood of graft failure after primary ACL-R was 0.86 times lower. A biomechanical study [27] that tested 6 to 9 mm hamstring allograft diameters suggested that increasing tendon graft diameters by 1 to 2 mm will significantly lead to better graft strength.

In regard to group B with the ACL-LET combination, graft failure occurred in one (2.1%) of 47 cases. This is comparable to the multicentric study of Getgood [4]. Graft-failure after the ACLR-LET combination was 4% out of 291 patients after 2 years. In a systematic study with an ACLR-LET combination, Grassi et al. [28] reported an ACL graft failure rate of 3.6% after different follow-up periods. After 20 years, in their long-term study with the ACLR-LET combination, Zaffagnini et al.[29] found a failure rate of 2% of 52 patients

Rotatory instability markedly improved from preoperative to postoperatively, as identified by the pivot shift test (Fig. 5). In regard to group A, a positive pivot shift test was detected in 3 (6.5%) patients. This is comparable to Jurkonis et al.[30], who found a positive pivot shift test in 8% of 88 patients, after 2 years with a graft diameter of 10 mm. To our knowledge, no other report in the literature, tested the role of graft diameter on rotatory laxity.

In regard to group B, a positive pivot shift test was detected in one (2.1%) patient. However, Guzzini et al. [31] found in a group of female players after 4 years of combined reconstruction a positive pivot shift test grade I in 6.3% of their patients. Grassi et al. [14] found in their systemic review of 628 patients that 15% of patients with the ACLR-LET combination had a positive pivot shift test grade I, 1% had a grade II, and 1% had a grade III. These findings would actually support the conclusion of the review by Dodds et al.[32], who stated that, the combined ACLR-LET reduces residual pivot shift test and improves the postoperative kinematics of the knee.

The combination of ACLR - LET (group B) decreases rotatory instability more than a triple graft ACL-R, with increased diameter (group A). The positive pivot shift test at follow-up (Fig. 5) was 2.1% versus 6.5%, respectively. However, the difference was statistically non-significant (*P*-value 0.32234). Biomechanical cadaver studies [33] support this conclusion; an ACL-R alone may be insufficient to restore internal tibial rotation to normal knee values, but a combined ACLR-LET can restore its rotational laxity. Zaffagnini et al.[21] reported that, extraarticular augmentation reduces the stress on the intraarticular portion of the graft, allowing better integration and representing a restraint to peripheral rotations.

However, combined ACLR-LET can over-constrain internal rotation of the knee when the anterolateral capsule is intact [34]. Hence, there is a concern that the addition of LET to the lateral side of the joint may increase the risk of post-traumatic OA [4]. However, a recent systematic review found that, radiographic evidence of OA was not significantly increased in patients where ACL-R was augmented with LET compared to ACL-R alone [35].

In group A, the subjective IKDC score was 90.94% (Table 2). This agrees with Rhatomy et al.[36], who found the IKDC score was 85.07 for the group with a large graft diameter of > 8 mm. Jurkonis et al.[30] found the subjective IKDC score to be 89.24 after 2 years with a graft diameter of 10 mm. In group B, the subjective IKDC score was 91.9 points (Table 2). This is comparable to Zaffagnini et al.[21] in their study, the IKDC score was 94.3 points for the ACL-LET combination. However, this score is better than Grassi et al. [28], who found in their systemic analysis to the combination of ACLR-LET, the IKDC score was 83.3 points. Getgood et al.[9] found in their multicenteric study with a combination of ACLR- LET on 589 patients, the IKDC score was 87.3% after 2 years.

The subjective IKDC score is a predictive factor for the return to sports [37]. Excellent IKDC scores (58 (63%) patients) were associated with a return to sport participation at a previous level in the current study (Table 6) than patients with lower scores. This agrees with Cheecharern et al. [37], who found high IKDC scores were associated with sports re-participation.

Objective IKDC scores were normal or nearly normal in group A in 43 (93.4%) patients (Table 2). Similar results were obtained by Jurkonis et al.[30].The score was 94.3%, with a graft diameter of 10 mm.

Regarding group B, objective IKDC scores were normal or nearly normal in 44 (95.6%) patients (Table 2). Grassi et al.[28] found the scores in a combined ACLR-LET to be normal or nearly normal in 86.2% of patients. Ferretti et al.[38] found it normal or nearly normal in 100% of patients after 10 years.

In this study, the relationship between the clinical outcome and age, weight (BMI) and gender were examined. Concerning age correlation, age had a significant negative correlation to the subjective IKDC (in both groups A and B, *p* value < 0.00001) (Table 3). This result agrees with Magnitskaya et al. [39], who found patients below 30 years of age had higher IKDC score values within the first year of primary ACL-R. This means that being younger is associated with higher clinical performance.

BMI had a non-significant correlation with IKDC scores (*p* value was 0.257742 for group A and 0.495094 for group B) (Table 4). However, Kowalchuk et al.[40], found higher BMI was correlated with lower IKDC scores. Gender had no correlation with IKDC scores (Table 5). This agrees with Tan et al.[41], in a systemic review, who found IKDC scores were comparable between sexes.

The aim of ACL surgery is to improve knee stability, minimize the chance of failure, and optimize the return to pre-injury levels of sports. According to this study, this can be achieved by increasing the graft diameter or by combing it with extra-articular augmentation, or by both techniques in one patient.

As a conclusion, both large graft-diameter and combination with extra-articular tenodesis decrease ACL-graft failure rates, postoperative rotatory instability and improve clinical outcome. However, the combination of anterior cruciate ligament reconstruction with extra-articular tenodesis was more effective than large-sized graft cruciate ligament reconstruction.

The limitations of the study include that, most patients were not sports players and were not involved in contact pivoting sports as a risk factor for return to sports. Along with this, a short follow-up period of 2 years. However, despite our appreciation of the limitations of our investigation, we believe that the results of this study could be useful in the future development of prospective comparative studies.

Declarations

Conflict of interest, Disclaimer: none, no thing to disclose.

Funding: no funding received for this research or its publication.

Colour: Only figure 2 and 4 require colours, but the rest require no colour for printing.

Consent: Informed consent was obtained from all individuals included in the study for participation and publication.

Ethic committee approval: Sohag Faculty of medicine, Sohag University, Egypt. IRB Approval nr. 153/2018.

Availability of data and material: data and material are available to all authors.

Policy: All authors agree to the journal of Archives of Orthopaedic and Trauma Surgery policies

Authors' contributions: all authors participate actively in the research.

Acknowledgment: Thanks to Arafa Elhawary for his illustrations. Thanks to Dr. Khaled Abo Gabal, Dr. Mohamed Omar for participation in the study, Mr. Willi Koll for English check and Mr. Peter Hans for statistical work up.

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Figures

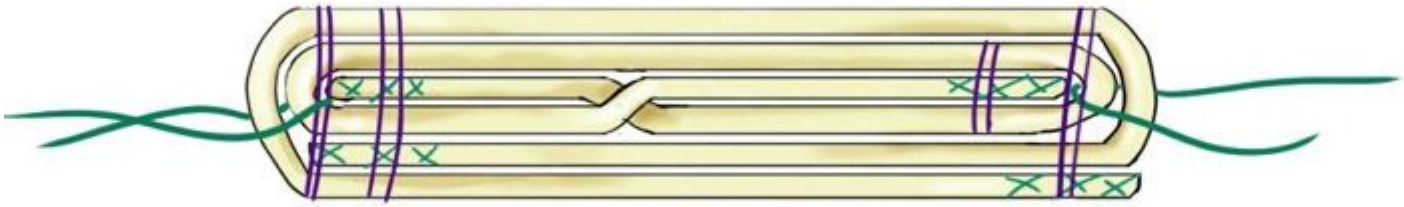

Figure 1

Illustration showing folding of STG graft three times, triple graft.

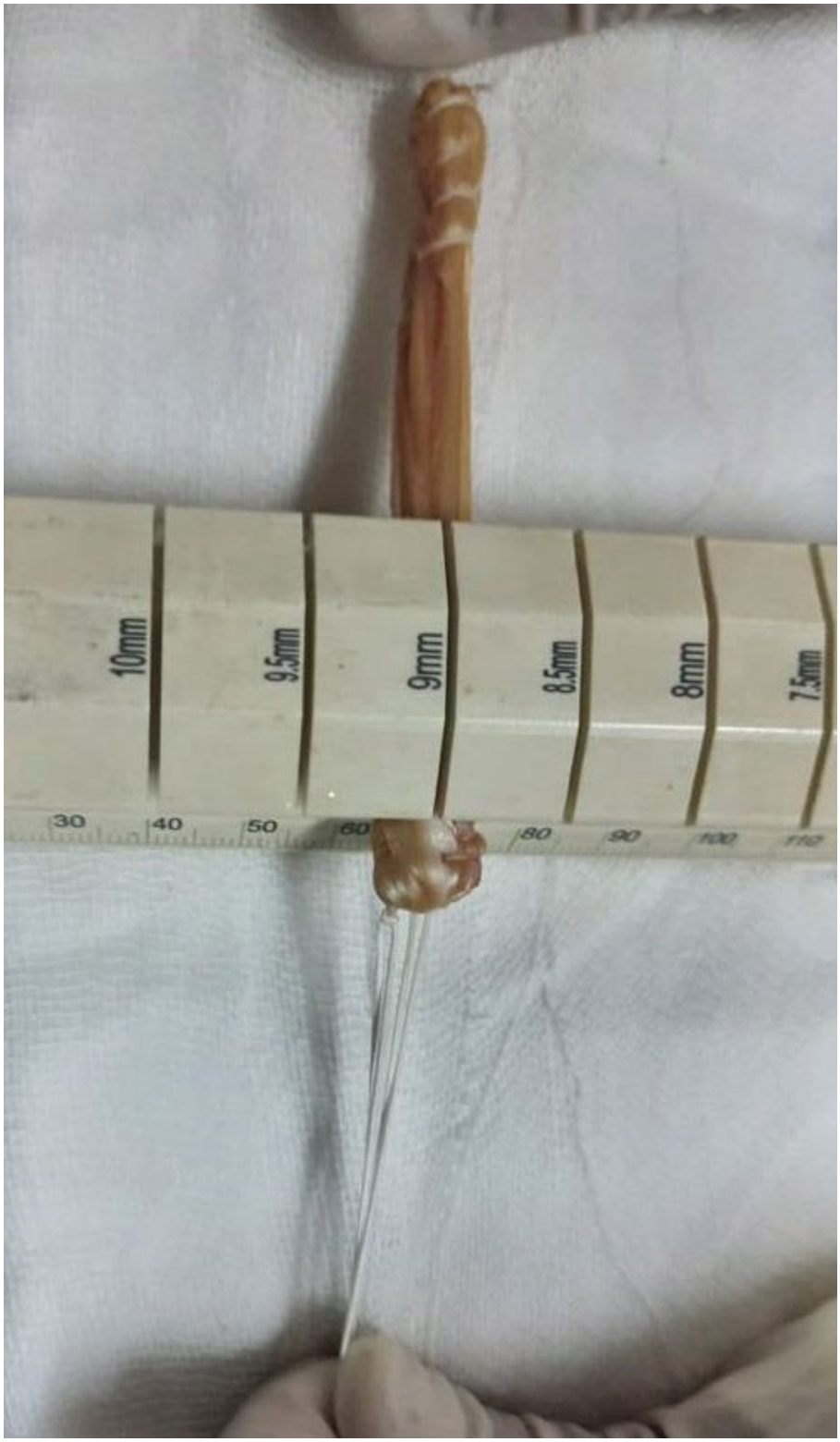

Figure 2

Intraoperative photo showing the triple graft after preparation

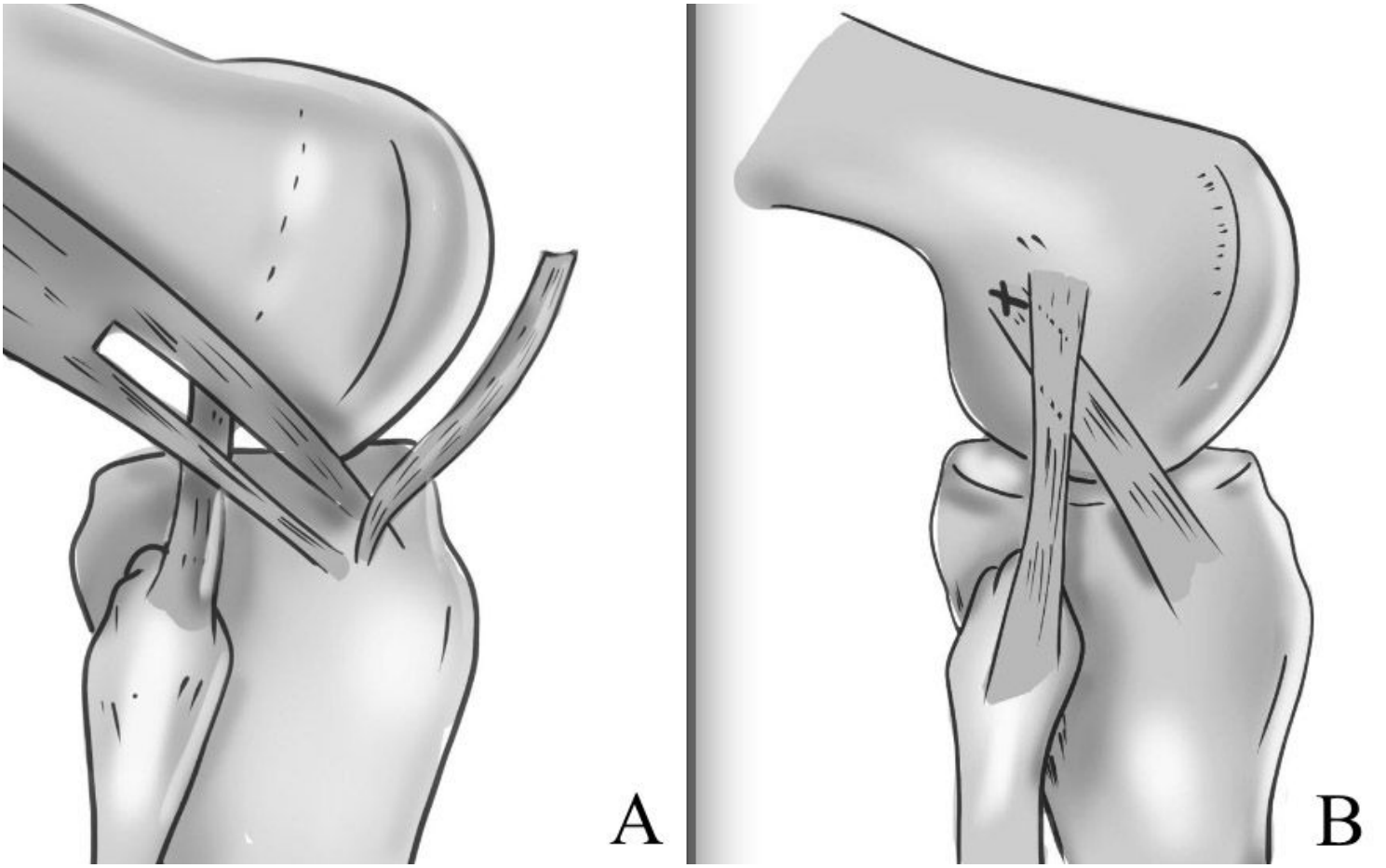

Figure 3

Illustration showing the steps of technique of extraarticular arthrodesis (Modified Lamaire) in A and B.

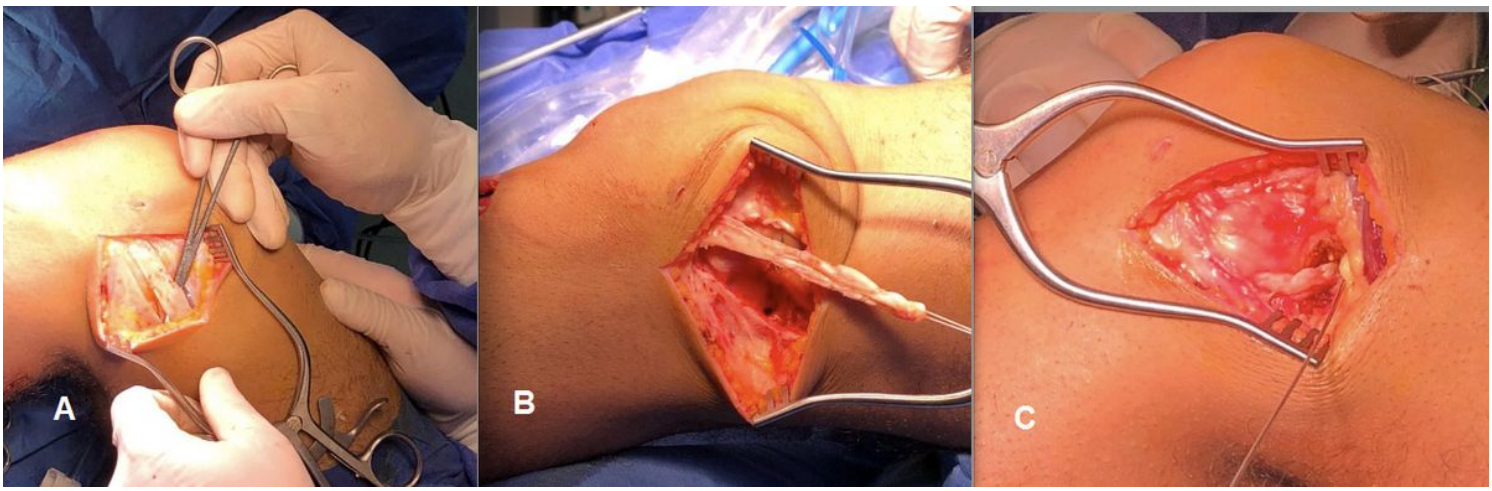

Figure 4

Intraoperative photo showing steps of extraarticular arthrodesis with the modified Lamaire method in A-C.

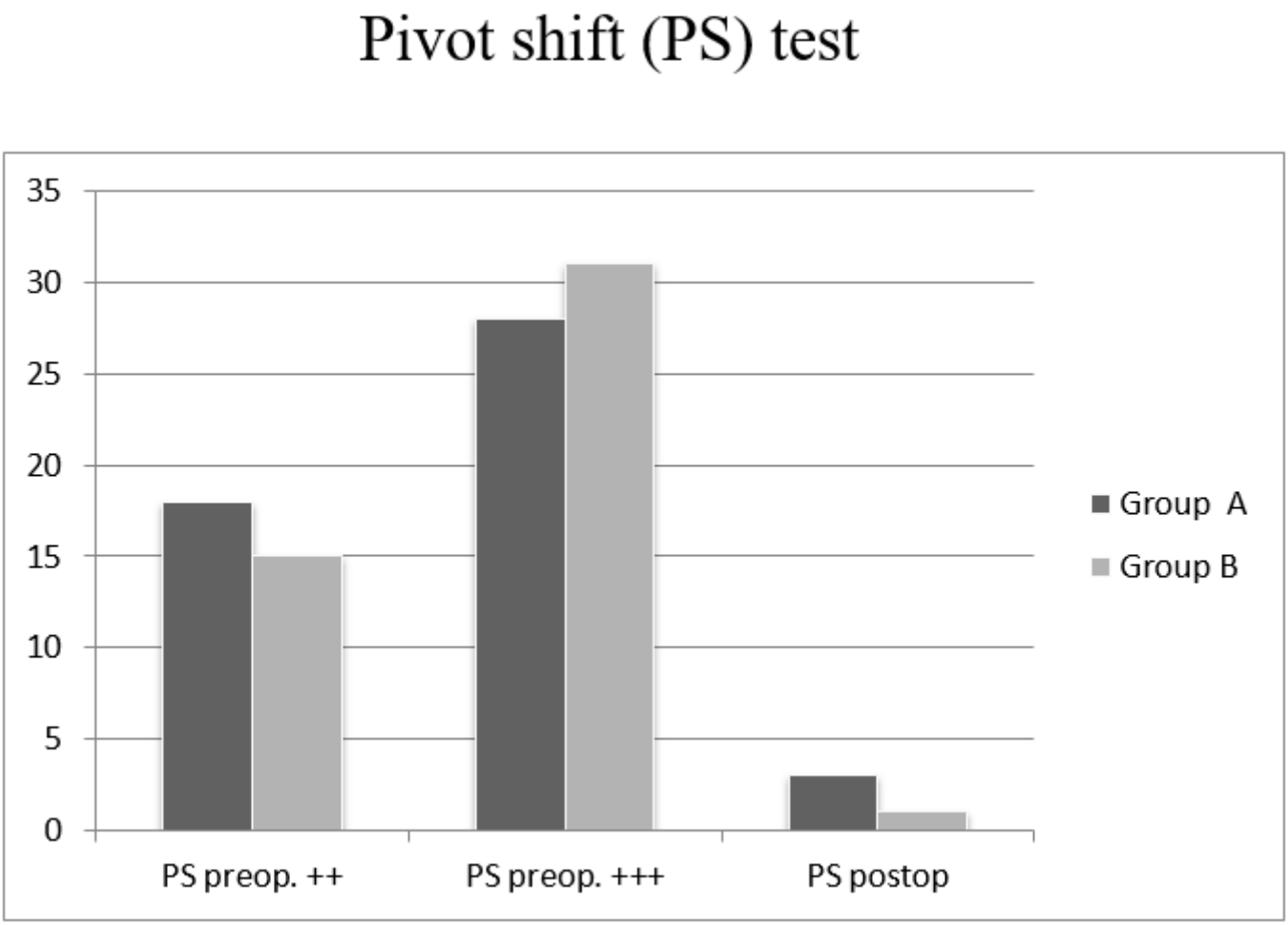

Figure 5

Chart shows pivot shift test before the operation and at follow up.