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A Randomized Controlled Trial of Femoral Tunnel Fixation Devices, Aperture Fixation by Screw Vs. Suspensory Fixation by Endo-Button in Arthroscopic Anterior Cruciate Ligament Restoration.

Hussain Bux Palh[1]*, Abdul Rahman khan[2], Hassan Amir us Saqlain[3], Malik Wasim Ahmed Majoka[4], Nadeem Hassan[5], Aurangzeb Husain Qureshi[6]

[1] *Hussain Bux Palh, Assistant Professor Orthopedic, Gambat Medical College Pir Syed Abdul Qadir Shah Jeelani Institute of Medical Science GIMS Gambat Pakistan.*
Email: drhussainpalh@gmail.com
[2] *Abdul Rahman khan, Assistant Professor Orthopedic Surgery, Dow International Medical college, Dow university Hospital, ojha Campus, Karachi Pakistan.*
Email: rehman.khan@duhs.edu.pk
[3] *Hassan Amir us Saqlain, Orthopedic Consultant, Al Qassimi Hospital Sharjah UAE.*
Email: hsaqlain1972@yahoo.com
[4] *Malik Wasim Ahmed Majoka, Assistant Professor Orthopedic Surgery, Dow International Medical college, Dow university Hospital, ojha Campus, Karachi.*
Email: bonemendor2015@gmail.com
[5] *Nadeem Hassan, Medical officer, Pakistan Institute of Medical Sciences Islamabad Pakistan.*
Email: Fad1988@yahoo.com
[6] *Aurangzeb Husain Qureshi, Assistant Professor Orthopedic, Niazi Medical and Dental College Lahore Road Sargodha Pakistan.*
Email: aurangzebq@gmail.com

***Correspondence author:** Hussain Bux Palh (drhussainpalh@gmail.com)

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Abstract

Background: With 200,000 cases in the US each year, anterior cruciate ligament (ACL) tears are among the most common sports-medicine injuries. Ligament repair has been demonstrated to be the most important barrier to anterior tibial translation (ATT) in the knee deficient in the ACL, especially for those who want to resume pivoting and highly competitive sports. Objective: The study was aimed to evaluate the outcomes of suspensory and aperture fixation methods for restoring soft tissue allografts in the anterior cruciate ligament (ACL). Study Design: A randomized controlled trial. Place And Duration: This study was conducted in Gambat Medical College Pir Syed Abdul Qadir Shah Jeelani Institute of Medical Science GIMS Gambat from August 2022 to August 2023. Methodology: A RCT was conducted after the formal approval from ethical review committee and obtaining the consent from the patient. All the patients admitted anterior cruciate ligament restoration were included in the study. Patients aged from 18 to 50 years who reported to have anterior cruciate ligament injury and chose to undergo reconstruction. Patients without any past history of anterior cruciate ligament reconstruction history were made part of the study. We used the SPSS version 25.0 for data entry and analysis. For the quantitative variables, means and standard deviations were computed; for the qualitative variables, frequency and percentages were given. Results: The mean age of the patients in aperture fixation group was 39.89 (SD ±3.76) years and 38.42 (±3.12) years in suspensory fixation group. In the aperture fixation group, there were 10 (55.6%) patients with right sided injury and in the suspensory fixation group there were 12 (66.7%) patients with right sided injury. The outcomes measures according to IKDC preoperatively and postoperatively at different follow ups at 1st, 4th, 8th and 12th month showed no any significant difference in surgical outcomes of the both procedure in the study. Conclusion: Our data revealed no any significant differences in outcomes after a 12-month follow-up between ACL allograft surgery conducted utilizing aperture fixation and ACL allograft repair performed using suspensory fixation.

Keywords

Anterior Cruciate Ligament, Suspensory, Aperture Fixation.

Approximately 200,000 anterior cruciate ligament (ACL) tears occur annually in the United States, making it one of the most common sports-medicine injuries [1, 2]. The most important restriction on anterior tibial translation (ATT) in the knee deficient in the ACL has been suggested to be ligament repair, especially for those who want to resume pivoting and highly competitive sports [3]. On the other hand, there is now more interest in arthroscopic primary ACL repair because to recent advancements in acceptable patient selection criteria, minimally invasive surgical techniques, and modern rehabilitation regimens [4, 5].

The ACL damage mostly affect persons who participate in pivoting sports (for example, football, basketball, netball, soccer, gymnastics, and downhill skiing). Graft fixation is one of the numerous factors of primary anterior cruciate ligament restoration (ACL-R) utilizing hamstring tendon (HS) autografts that might impact clinical results. In the immediate postoperative phase, graft fixation is generally seen as the weakest link [6, 7]. The second-most critical element in determining the integrity and effectiveness of ACL-R is suspensory graft fixation versus aperture graft fixation [8].

A variety of factors determine the kind of graft fixation used, including surgeon preference and training, cost, convenience of use, and clinical experience [9]. The optimum ACL-R connection technique must be sturdy, stiff, and non-slip. Furthermore, it has been proven that graft attachment method influences the probability of revision following ACL-R [10]. Suspension fixation techniques, according to research, offer greater pull-out capabilities than multiple aperture fixation techniques [6, 11, 12].

There is published research that increased knee stability and decreased graft-tunnel motion under anterior tibial loading, other studies have discovered potential risks associated with aperture fixation techniques, such as the possibility of tunnel blow-out and the screw's ability to affect tendon-to-bone healing [13]. When it comes to suspensory fixation vs soft-tissue graft-aperture fixation, there is no clear consensus on the best strategy for graft fixation [14].

The present study was aimed to compare the outcomes of two surgical techniques for graft fixation, using randomized control trial. It was hypothesized that any of the procedures might prove comparatively better. The refore this study included two random groups to evaluate the outcomes of the procedures.

Methodology

A RCT was conducted after the formal approval from ethical review committee and obtaining the consent from the patient. All the patients admitted with anterior cruciate ligament restoration were included in the study. There were two methods chosen for restoration, i. femoral side endobutton and tibial cortical interference screw and ii. Femoral and tibial joint-line fixation with screws. The former is named as aperture fixation and later is named as suspensory fixation.

Inclusion Criteria: We included the patients aged from 18 to 50 years who reported to have anterior cruciate ligament injury and chose to undergo reconstruction. Patients without any past history of anterior cruciate ligament reconstruction history were made part of the study.

Exclusion Criteria: Those patients who reported to have any previous ACL procedure or meniscus injury, or injury to lateral collateral ligament, postero- lateral corner of the knee, medial collateral ligament, and posteromedial corner posterior cruciate ligament were excluded. Also the patients who didn't consent to part of the study were excluded.

We used the knee form designed by IKDC to collect patient's socio- demographic data, the age and gender, as well as surgical observations of meniscal and cartilage damage, prior to surgery. The key outcome indicator after surgery was the knee IKDC score at a 1, 4, 8, or 12-month follow-up. As secondary end measures, the anterior drawer displacement knee evaluation and knee examination scores at 1, 4, 8, and 12 months were used to quantify joint laxity. We also documented the side effects of the surgeries.

Procedures in the study

The allograft reconstructions were carried out under the spinal anesthesia. We used ethibond 5.0 sutures to whip stitch the hamstring tendon grafts. The anteromedial portal approach was used to establish femoral sockets using a spade-tip Beath pin and low-profile reamers, and a tibial jig was used to make tibial sockets (Arthrex). All the grafts were soaked in normal saline. For the aperture fixation we employed a tibial interference screw 1 mm smaller than tibial socket and a titanium femral interference screw 1 mm smaller the femoral socket

For the suspensionfixation (Arthrex), we tied the tibial sutures and femoral end button on titanium cortical button. During fixation, the grafts were manually tightened utilizing a tibial-side tensioning method. The rehabilitation after the procedure includes an emphasis on full extension right away, straight-ahead running three months later, and pivoting six months later.

Statistical Analysis

We used the SPSS version 25.0 for data entry and analysis. The means and standard deviations were calculated for quantitative variables and frequency and percentages were reported for the qualitative variables. To compare IKDC knee examination results, a statistical test was applied, and analyses were carried out in cooperation with a biostatistician. Data were gathered and recorded at two weeks, one month, four months, eight months, and twelve months.

Results

In the present study we inducted 36 patients, 18

patients were randomly assigned in each group, and that is, 18 patients in suspensory fixation group and 18 patients in aperture fixation group.

In the aperture fixation group, there were 15 (83.33%) male and 3 (16.67%) females and in the suspensory fixation group there were 14 (77.78%) males and 04 (22.22%) females.

In the aperture fixation group, there were 10 (55.6%) patients with right sided injury and 8 (44.4%) left sided injury and in the suspensory fixation group there were 12 (66.7%) patients with right sided injury and 06 (33.3%) with left sided injury. The mean age of the patients in aperture fixation group was 39.89 (SD ±3.76) years and 38.42 (±3.12) years in suspensory fixation group. (As shown in Table I).

Table I. Distribution of Gender, Side of Injury and Age.

Variables	Aperture		Suspensory		Statistics	P value
	Frequency	%	Frequency	%		
Gender						
Male	15	83.33	14	77.78	0.51	0.38
Female	03	16.67	04	22.22		
Side of Injury						
Right	10	55.60	12	66.70	0.24	0.65
Left	8	44.40	6	33.30		
Age (mean SD)	39.89 (±3.76)		38.42 (±3.12)			0.52

The outcomes measures according to IKDC preoperatively and postoperatively at different follow ups at 1st, 4th, 8th and 12th month showed no any significant difference in surgical outcomes of the both procedure in the study. (As shown in Table II)

Table II. IKDC Distribution of Patients Included in the Study.

	Suspensory	SD	Aperture	SD	P value
Postoperative					
1 month	59.8	2.6	62.7	2.1	0.23
4 month	72.6	3.6	74.9	3.9	0.15
8 month	79.9	4.2	81.4	4.3	0.44
12 month	89.2	4.7	90.3	4.4	0.36
Preoperative	46.9	1.9	47.3	1.5	0.52

Discussion

In the present study we inducted 36 patients, 18 patients were randomly assigned in each group, and that is, 18 patients in suspensory fixation group and 18 patients in aperture fixation group. Our sample size was comparatively lesser than used by Schliemann B et al[15] and slightly greater than the sample size used by Pandey SK et al with sample size 30[16]. In the aperture fixation group, there were 15 (83.33%) male and 3 (16.67%) females and in the suspensory fixation group there were 14 (77.78%) males and 04 (22.22%) females. The distribution gender was nearly similar in the study conducted by Pandey et al [15], the predominance of man in the patients in reasonably understandable due to their involvement in sports and outdoor activities [17]. However, Lowenstein NA et al used a sample with greater number females in a similar study [18].

In the aperture fixation group, there were 10 (55.6%) patients with right sided injury and 8 (44.4%) left sided injury and in the suspensory fixation group there were 12 (66.7%) patients with right sided injury and 06 (33.3%) with left sided injury. The mean age of the patients in aperture fixation group was 39.89 (SD ±3.76) and 38.42 (±3.12) in suspensory fixation group. The findings of our study stay in line with the findings of Pandey SK et al [16] and research conducted by Sporsheim AN in 2019 [19]

The outcomes measures according to IKDC preoperatively and postoperatively at different follow ups at 1st, 4th, 8th and 12th month showed no any significant difference in surgical outcomes of the both procedure in the study. The major finding of our study is supported by a meta-analysis by Ilahi et al. [21], which also reveals no clinical differences between intra-tunnel fixation and extra-tunnel fixation of soft-tissue ACL repair grafts [20-23].

Meanwhile Shen Z et all, [24] emphasized that Short-term results for ACL repair and reconstruction appear to be equal. The low rate of revision following first repair is promising. Current repair approaches, such as dynamic intraligamentary stabilization and bridge-enhanced ACL repair, may be an effective alternative to reconstruction for individuals with ACL damage.

Limitation of the Study

Our study's primary shortcoming is the tiny patient sample size. Moreover, we excluded those individuals who were older than 50 years. Due to the limited sample size, an examination of subgroups was not conducted. Because of the short sample size, less than 90% of normal ratings could be obtained with a bigger sample size.

Conclusion

Our data revealed no any significant differences in outcomes after a 12-month follow-up between ACL allograft surgery conducted utilizing aperture fixation and ACL allograft repair performed using suspensory fixation.

Competing Interests

The authors declared no any conflict of interest.

Funding Resources

There were no any funding resources involved.

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