

Effectiveness of One-year Functional Outcomes in Anterior Cruciate Ligament Reconstruction Using Internal Brace Augmentation in All-Inside Graftlink Technique with Allograft

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Abstract

Background: The anterior cruciate ligament (ACL) has a rupture incidence in the USA of 1/3,000 and 250,000 ruptures per year. The highest incidence is between ages 16 to 39. ACL injuries often occur with other knee injuries. The goal of ACL trauma treatment is to restore joint function short-term and prevent long-term degenerative changes. The allograft surgical technique requires structural support during the first 12 postoperative months. Internal brace suture augmentation, supported by biomechanical and clinical studies, aim to reduce the recurrence risk.

Materials and Methods: A prospective comparative study assessed the functional outcomes of ACL rupture patients who underwent the All-Inside GraftLink technique with allograft. It compared 13 patients with internal brace augmentation to 22 without it. Using IBM SPSS version 10, inferential analysis, including Shapiro-Wilk tests for normality and graphical methods for central tendency, was performed. Descriptive statistics, such as mean \pm standard deviation and median, were calculated.

Results: A functional improvement trend was observed with internal brace augmentation, showing statistical significance ($P < .005$) from the first month. This improvement persisted up to one year, supported by corresponding cohort time points, affirming our alternate hypothesis. Conclusions: This study demonstrated that for patients with ACL rupture requiring invasive treatment, the surgical technique with allograft and internal brace augmentation provides an additional advantage by decreasing strain on the allograft during rehabilitation. This benefit considers the demands of sports activities and concomitant injuries, leading to improved functional outcomes perceived by the patient. Consequently, this surgical technique is highly recommended.

Keywords: anterior cruciate ligament rupture; anterior cruciate ligament reconstruction; augmentation; internal brace; allograft; IKDC score

Abbreviations

ACL: Anterior cruciate ligament

MRI: Magnetic resonance imaging

OA: Osteoarthritis

BTB: Bone - patellar tendon - bone

IKDC: International Knee Documentation Committee

Introduction

Ligaments are well-organized structures whose function is to protect and stabilize the joints, allowing the mobility and maintaining intra-articular

pressure and proprioceptive mechanisms. They are primarily composed of collagen fibers, mainly type I (90%) [1-2]. The knee joint is the largest joint in the body and one of the most complex [3]. It's a mobile anatomical functional unit that has a crucial role in sports function [4]. The anterior cruciate ligament (ACL) is an intra-articular and extrasynovial structure. Its proximal insertion is located on the posterior part of the inner surface of the lateral femoral condyle, and it inserts distally in the anteromedial region of the tibial plateau between the tibial spines [5]. The ACL has limited vascularization, relying on the middle genicular artery for blood supply, and it is innervated by branches of the tibial nerve. The ACL's average length ranges from 31-38 mm with a thickness of 11 mm. It consists of two bundles:

the posterolateral and anteromedial bundles [5]. The anteromedial bundle is more susceptible to trauma when the knee flexes and rotates 90°. When the knee extends, the posterolateral bundle tightens [5].

The incidence of ACL rupture in the USA is 1 / 3,000, [5], with approximately 250,000 cases annually [9]. The peak incidence occurs between the ages of 16 to 39 [6]. Female athletes are 2-9 times more likely to suffer an ACL injury compared to males [10]. The ACL does not regenerate on its own after injury due to its poor vascularization and low cellular capacity for new collagen production. [11]. Leading to about 100,000 reconstructions performed annually [5]. ACL injuries often occur with other concomitant injuries of the knee [7]. The prevalence of associated injuries in the medial collateral ligament and meniscus is 30% and 42%, respectively, with combined meniscus and cartilage injuries in 15% of cases [11]. Between 70-84% of ACL injuries are non-contact injuries, typically occurs during deceleration activities such as cutting and landing on one leg during a jump, causing axial loading with valgus collapse and rotation [12]. Clinical symptoms include pain, mild swelling, and instability sensation. Physical examination reveals anteroposterior and anteroexternal laxity using the Lachman and Pivot-Shift tests [5]. Over time, the knee experiences joint failure and femorotibial subluxation, leading to secondary joint damage (meniscal, chondral, and capsuloligamentous injuries), increasing joint laxity and progressive articular degeneration [5]. The risk of osteoarthritis (OA) increases with BMI, physical inactivity, quadriceps weakness, and concomitant injuries. [9]. 20-50% of patients have radiographic findings of OA after joint trauma, with a relative risk of OA after ACL injury being 3.89-7 times higher than in uninjured patients [13]. The primary goals of ACL trauma treatment are to restore joint function in the short term and to prevent long-term degenerative changes in the knee. [5]. Surgical reconstruction aims to maximize knee stability for a return to daily-life and sports activities. The success rate of surgical procedures ranges from 75-97%, but the return to pre-injury sport levels is only 65%. [14]. The choice of graft for ACL reconstruction is debated. Common grafts include bone-patellar tendon-bone (BTB), quadriceps, and hamstring tendons, as well as allografts. Hamstring grafts have a slightly higher re-rupture rate compared to BTB [15]. However BTB graft is associated with more anterior knee pain. [15]. Autografts are preferred due to their similarity to native ACL [5], and have the advantage of the absence of foreign body response, though they have disadvantages like donor site pain and reduced range of motion, potentially delaying rehabilitation. Allografts offer shorter surgical time and no donor site morbidity but increase the risk of graft rejection and disease transmission. Although autografts have more risk of failure and revision surgery [11,17]. ACL reconstruction with concomitant meniscal repair can restore knee kinematics and lead to better patient-reported outcomes in short- and long-term follow-ups [7]. The use of allografts reduces the ligament's ability to withstand the traction force caused by knee joint movement. [8]. Setiawan et al suggest that ACL reconstruction should be protected from total weight bearing for a longer period of time, leading to the implementation of an internal brace suture technique in biomechanics models and clinical settings, proposed as an intervention potentially reducing the risk of recurrence [11]. Suture augmentation with internal brace has been implemented and proposed as an intervention that potentially decreases the risk of recurrence [18]. It consists of a high molecular weight braided suture tape made of polyester and polyethylene, which functions without knots and anchors to the bone to reinforce the ligament, providing a stabilizing structure for rehabilitation and preventing secondary injuries [19]. This approach can be useful to reduce the rate of new injuries and improve knee function during the early healing phase, potentially enhancing the overall surgical outcome for patients. This technique is particularly advantageous for active patients and those with smaller graft diameters [8]. Other ligament augmentation techniques have reported intra-articular complications [18]. The IKDC (International Knee Documentation Committee) is a commonly used tool for evaluating

outcomes after knee surgery. The IKDC knee score consists of an assessment of the knee (10 items) and a checklist of knee ligaments (eight items), covering joint pain, motor function, and daily activity capacity, with a total score ranging from 0 to 100. The IKDC can be used to assess symptoms, function, and physical activity of the knee [19]. The objective was to evaluate their functional outcomes using the subjective IKDC scale over a one-year follow-up period, utilizing monthly, semi-annual, and yearly cohort points.

Materials and Methods

A literature review of research studies on surgical intervention for complete ACL rupture led to the decision to conduct a longitudinal prospective analytical research study. The study included a population of 108 patients with complete ACL rupture who underwent surgical procedures from April 1, 2020, to February 1, 2022, at the Hospital Español de México. A sample of 35 patients underwent surgical reconstruction using the All-Inside GraftLink technique with allografts, with 13 receiving allograft augmentation using internal brace and 22 without this procedure. This study was approved by the ethics protocol of our institution. A prospective observational cohort study, with a minimum follow-up of 12 months after the surgical procedure. The patients were diagnosed and treated surgically by two orthopedic physicians at the Hospital Español de México. The diagnosis of anterior cruciate ligament total rupture, as well as other concomitant knee injuries (meniscal tears) was established by simple magnetic resonance imaging of the knee [5]. Once they met the inclusion and exclusion criteria (which are detailed below): for the study protocol, their data was recorded in a database, which only the treating physicians have access to. The foregoing in order to follow up on the day of his surgical intervention and in his post- surgical evolution The study included 108 patients with total rupture of the anterior cruciate ligament (ACL). Among these patients, 35 were diagnosed with complete ACL rupture and underwent surgical reconstruction using the All-Inside GraftLink technique with allograft. Thirteen of these patients received augmentation of the allograft with an internal brace, while 22 did not undergo this procedure. The study period ranged from April 1, 2020, to February 1, 2022, at the Hospital Español de México. Our selection criteria were the following. *Inclusion criteria:* Patients diagnosed with ACL rupture who were admitted to the Hospital Español de México from April 2020 to February 2022 for ACL reconstruction using the All-Inside GraftLink technique with allograft; Aged between 18 and 50 years; Undergo a total postoperative follow-up of 1 year; Other meniscal injuries that do not interfere with the rehabilitation process. *Exclusion criteria:* Patients with a complete ACL rupture admitted to the Hospital Español de México from April 2020 to February 2022 for reconstruction using a surgical technique other than All-Inside GraftLink; Did not undergo a total follow-up of 1 year; Multiligamentous injuries; Injuries in both knees; Articular cartilage lesions; Unable to undergo appropriate rehabilitation or injuries that compromise or delay the rehabilitation process. Data Analysis: Inferential analysis was performed using IBM SPSS version 10. Normality tests such as Shapiro-Wilk were used for quantitative variables, and graphical methods were employed to assess central tendency. Descriptive statistics including mean \pm standard deviation and median were calculated. The comparative analysis of quantitative variables will be conducted to correlate functional evolution with the IKDC scale based on the use of internal brace or lack thereof using the Student's t-test and Mann-Whitney U test, with a normal population distribution. The Chi-square test will be employed for independent qualitative variables. All tests will be performed with a significance level set at $p < 0.05$. Finally, correlation analysis will be conducted to determine variables with positive or negative associations with patient evolution using Pearson's correlation coefficient.

Results

We observed that our patients have a mean age of 31.9 ± 7.3 years, with men predominating at 65.7%. They have a mean BMI of 24.7 ± 2.8 kg/m², on average 24.3 kg/m², suggesting a normal BMI. However, upon sub

classifying our sample according to BMI classification models, we find that while 60% had normal BMI data, up to 37.1% (13) were overweight. (Table 1) It is noteworthy that 7 (53.8%) of them were approached without an internal brace and 6 (46.1%) with this technique, which will not influence the functional evolution results.

	n=35	
	Mean \pm SD	Median
Age	31.9 \pm 7.3	32
Sex (n%)		
- Male	23 (65.7%)	
- Female	12 (34.3)	
BMI (Kg/m ²)	24.7 \pm 2.8	24.3
BMI Classification (n%)		
- Normal range	21 (60%)	
- Overweight	13 (37.1%)	
- Obese class 1	1 (2.9%)	

Table 1. Population Characteristics; BMI: Body Mass Index;

Comparing the clinical characteristics of our patients regarding injuries associated with ACL rupture, we see that the lateral meniscus predominates in the total sample (28.6%) and does not have a prioritized distribution according to the placement of internal brace or not (50%-50%), which does

not occur with injuries of the medial or both (medial and lateral) meniscus, where their distribution is concentrated in patients who did not undergo an internal brace augmentation. Regarding graft size, a median of 10mm was managed for all patients. (Table 2).

	Total Population N=18	Surgical Technique with Internal Brace n=13 (37.1%)	Surgical Technique without Internal Brace n=22 (62.9%)	p value
Associated injuries				.582
Medial meniscus	6 (17.1%)	2 (46.2%)	4 (18.2%)	
Lateral meniscus	10 (28.6%)	5 (38.5%)	5 (22.7%)	
Medial and lateral meniscus	2 (5.7%)	0	2 (9.1%)	
Graft size (mm)	9.1 ± 1.3	9 ± 1.3	9.2 ± 1.3	.601
<u>Mean + SD</u>				
Median	10	10	10	

Table 2. Associated knee injuries and graft size. Using Chi-square test; SD: Standard deviation

In the study, the functional scale (IKDC) was compared between patients who underwent surgery with the placement of an Internal Brace (n=13) and patients who underwent surgery without the placement of an Internal Brace (n=22). All patients were evaluated over a year with the following postoperative time points: one month, six months, nine months, and one year of follow-up. As a result, a higher score was obtained in those patients with the placement of an Internal Brace from the first postoperative month (49.06

vs. 42.2; p 0.001). This score was maintained throughout the follow-up at six months (59.06 vs. 53.5; p 0.003), and at nine months (75.8 vs. 70.6; p 0.001). Finally, at the one-year follow-up, this functional improvement continued (98.03 vs. 94.1; p 0.002) (Table 3).

	IKDC (%) 1 month	IKDC (%) 6 months	IKDC (%) 9 months	IKDC (%) 12 months
SURGICAL TECHNIQUE WITH INTERNAL BRACE N=13 (37.1%) Mean ± Sd	49.06 ± 4.3	59.06 ± 4.3	75.8 ± 3.8	98.03 ± 2.8
Median	50	58.2	74.9	100
SURGICAL TECHNIQUE WITHOUT INTERNAL BRACE N=22 (62.9%) Mean ± Sd	42.2 ± 5.8	53.5 ± 5.01	70.6 ± 4.02	94.1 ± 3.5
Median	41.6	54.1	70.8	94.5
p - value	.001	.003	.001	.002

Table 3. IKDC Score with and without Internal Brace. Using Student T test; IKDC: International Knee Documentation Committee; SD: Standard deviation.

Discussion

In 2019, Bodendorfer and colleagues compared the subjective outcomes reported by 60 patients (30 with and 30 without internal brace, using either autograft or allograft) and the return to sports at pre-injury levels. The IKDC results in patients with internal brace were superior (p=0.010). It was concluded that suture augmentation was a predictor for improvement in IKDC and other functional scales as it provides greater dynamic stability, especially in the early stages of graft healing, valuable for ACL recovery until sufficient healing allows for a stable graft [20].

Daniel A V. et al. in 2023 compared two groups undergoing ACL reconstruction with autograft, with or without internal brace (100 patients each), with similar demographic characteristics, in a minimum 2-year follow-up. The graft was prepared using the All Inside GraftLink technique, and the same rehabilitation program was used for both groups. The group without internal brace had a higher recurrence rate (8 vs. 1, p=0.017). Functionality scales and subjective outcomes in both groups were similar with no statistical significance. Internal brace augmentation reduced recurrence by 88%, as it improves the mechanical properties of the graft and distributes forces during the graft remodeling phase, aiding in the return to sports activities, especially in younger and more active patients[18].

The limitations identified in this research study are primarily based on the lack of records concerning the level of sports activity prior to the injury, the type of sport practiced, the duration of the injury before surgical intervention, limb dominance, and rehabilitation protocols both before and after the surgical intervention.

Conclusions

With this study, it is demonstrated that for patients with ACL rupture requiring invasive treatment, the surgical technique using augmented allograft with internal brace is an added benefit to improve the impact on the graft during rehabilitation, considering the demands of sports activities and the association of concomitant injuries, towards a perceived functional improvement by the patient, making it a highly recommended surgical technique.

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The content is solely the responsibility of the author.

Conflict of Interest

The research team is not in a conflict of interest situation regarding the conduct of this research project since there is no direct commercial or economic relationship with any sponsor, no direct professional relationship with any sponsor, and furthermore, there is no cause or reason that could affect the objectivity or independence in the performance of the functions of the researchers involved in this project.

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