Original Article

Comparative Study on Outcome of Early Aggressive and Standard Rehabilitation after Anterior Cruciate Ligament Reconstruction

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Abstract

Background: Anterior cruciate ligament rupture is one of the most common debilitating knee injuries that can result in significant functional impairment. Although ACL reconstruction (ACL-R) is a commonly practiced surgical intervention, controversy still lingers with regard to graft selection and rehabilitation protocol, both of which are largely influenced by surgeon preference. The post-operative restrictions are largely based on the theory of graft and fixation vulnerability, with concerns related to compromising the biological healing process of the reconstructed graft during the first 12 weeks postoperatively. To date, controversy still lingers in evaluating the effects that aggressive rehabilitation has on clinical outcomes with semitendinosus graft. The aim of this study was to investigate whether immediate full weight bearing combined with aggressive rehabilitation in ACL-R significantly altered postoperative outcome over one year, relative to a program that included partial weight bearing and standard rehabilitation protocol in the immediate post-operative period.

Methods: The study was a prospective randomized clinical trial, with all patients being recruited by a single senior orthopedic surgeon at our institute after a confirmed diagnosis of an isolated ACL rupture by clinical examination and magnetic resonance imaging. Seventy patients were enrolled in the study from June 2015 to August 2017. Informed consent was taken. Clearance from ethical committee of the institute was taken. Patients were evaluated pre operatively and post operatively at the end of 1, 3, 6 months and 1 year for outcomes.

Results: In this prospective study conducted with seventy patients, we found better results in group 2 (full weight bearing) as compared to group 2 (partial weight bearing) in terms of IKDC scoring, range of motion (ROM), ROM difference from opposite knee and fixed flexion deformity. The results were statistically significant.

Conclusion: We conclude that aggressive rehabilitation to be superior to standard rehabilitation after isolated ACL-R using STG .

.**Keywords**: ACL, ACL-R, Rehabilitation

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Introduction

Anterior cruciate ligament rupture is one of the most common debilitating knee injuries that can result in significant functional impairment.[1-3] Surgical reconstruction of a ruptured ACL is advocated as the treatment of choice, particularly for individuals who intend to resume competitive sporting activities[4-6]. Although ACL reconstruction (ACL-R) is a commonly practiced surgical intervention, controversy still lingers in

regard to graft selection and rehabilitation protocol, both of which are largely influenced by surgeon preference [7]. Traditional postoperative restrictions such as bracing for immobilization, delayed weight bearing, and limiting early hyperextension motion (beyond 0° of extension) have all been used throughout rehabilitation in hopes of preventing excessive loads on the healing graft [8]. The implications of these restrictions are largely based on the theory of graft and fixation vulnerability, with concerns related to compromising the biological healing process of the reconstructed graft during the first 12 weeks postoperatively [9-11]. These concerns have most appropriately been justified for Semitendinosus (ST) grafts due to the slower incorporation rate of the soft tissue into the bone tunnel and concerns of excessive graft-tunnel motion leading to increased laxity [12]. Granted that these theories are still valid concerns in postoperative management, advancements in surgical technique and fixation have warranted re-evaluation of the use of restrictions after ACL-R with gathering evidence showing that restrictions may not be necessary. Early aggressive rehabilitation has shown no adverse effects with respect to future injury rate, Antero-Posterior laxity, Range Of Motion deficits, or ability to return patients back to their previous level of function [12,13]. Although a significant body of literature has shown that aggressive rehabilitation defined as early unrestricted motion, immediate weight bearing, and eliminating the use of immobilizing braces to be appropriate after ACL-R using BPTB grafts conclusions are unclear when evaluating the effects of early aggressive rehabilitation on ST autografts [13-15]. To date, controversy still lingers in evaluating the effects that aggressive rehabilitation has on clinical outcomes with this particular graft. Some studies have shown that aggressive rehabilitation immediately after surgery tends to increase knee laxity [8,10], while others have found no difference in subjective outcomes or functional stability [16,17]. Furthermore, Wright et al conducted a systematic review confirming that the available evidence on postoperative bracing, immediate weight bearing, and unrestricted ROM has largely been performed addressing BPTB grafts, demonstrating the lack of attention in comparison with ST grafts [14]. Therefore, a need exists to evaluate the effects of early aggressive rehabilitation of ST grafts on mobility, strength, and self-reported outcome scores. The aim of this study was to investigate whether immediate full weight bearing combined with aggressive rehabilitation in ACL-R significantly altered postoperative outcome over one year, relative to a program that included partial weight bearing and standard rehabilitation protocol in the immediate post-operative period.

Materials and Methods

Seventy patients were enrolled in the study from June 2015 to August 2017. The study was a prospective randomized clinical trial, with all patients being recruited by a single senior orthopedic surgeon at our institute after a confirmed diagnosis of an isolated ACL rupture by clinical examination and magnetic resonance imaging. Two experienced physical therapists who were not involved in data collection treated all patients in both allocated groups. A single research assistant who was blinded to the treatment allocation measured all outcome variables. Patients were evaluated pre operatively and post operatively at the end of 1, 3, 6 months and 1 year for outcomes.

Inclusion criteria:

•Age 18 to 55 years

•Grade II or III isolated ACL tear confirmed by orthopedic surgeon

•Demonstration of full knee extension and at least 85% knee flexion preoperatively compared with the contralateral knee

•Ability to comply with a 24-week rehabilitation program.

•Unilateral pathology

•No previous knee surgery

Exclusion criteria:

•Any previous ACL-R to either knee

•Concurrent injury to the posterior cruciate ligament

•Grade III tear of either (medial or lateral) collateral ligament

•Meniscus tears ≥5 mm or meniscus repairs

•Pregnancy

•Neurological disorders (multiple sclerosis, cerebral palsy, etc) affecting participation

Patients with age above 50 years were excluded as age related degenerative changes are common after 50 years. After subjects provided consent for participation, the research assistant randomized them into one of two treatment groups by computer software randomization. A simple randomization technique was performed, and to conceal the treatment allocation, the randomization scheme was computer generated before initiation of the study. Patients were randomized into either the aggressive or the nonaggressive group.

Surgical Procedure

All patients underwent a single-bundle ipsilateral 4-strand ST autograft reconstruction. Confirmation of a complete ACL tear was accomplished arthroscopically, followed by preparation of the femoral notch and tibial footprint. The STGs were harvested in standard fashion through a 3-cm incision over the anteromedial tibia, then the graft was prepared with #5 Ethibond whip stitching the free ends of the graft. A tibial tunnel was reamed entering the anatomic center of the tibial ACL insertion. An accessory medial portal was created through which the femoral tunnel was placed in the anatomic center of the femoral ACL footprint. The tibial and femoral tunnels were sized to the diameter of the graft. The ACL fixation consisted of femoral button suspension fixation. Tibial fixation was accomplished using an interference screw with the knee positioned in 15° knee flexion with force applied as in doing posterior drawer test.

Rehabilitation

The aggressive group underwent a protocol that was largely derived from previous work described by Biggs et al 18 (Figure 1). Patients were not required to wear a postoperative knee brace and began exercises to restore full passive motion without restrictions on hyperextension immediately after surgery. Patients in this group were informed to begin weight bearing as tolerated immediately after surgery and to only use the bilateral axillary crutches for comfort. During the first postoperative week, patients underwent a rehabilitation regimen consisting of keeping activity to a minimum and remaining in a supine position while the leg was elevated at least 12 inches above the chest for at least 18 hours of the day, and beginning phase I exercises to initiate early motion and muscle activation. The nonaggressive group were required to wear a ROM brace locked at 20° of flexion for the first week and unlocked 10° to 100° for an additional 3 weeks after surgery. Patients were instructed to only remove the brace to perform the phase I exercises, and during physical therapy visits. They were required to wear the brace at night to sleep for the first week. After 4 weeks of postoperative bracing, the brace was discontinued and the treating physical therapists instructed patients to begin full passive knee-flexion motion, but they were restricted to no hyperextension stretching for

an additional 2 weeks postoperatively. Hyperextension exercises were defined as any active or passive stretch beyond 0° of knee extension. Patients in this group also used bilateral axillary crutches for 2 weeks postoperatively at 25% weight bearing for the first week and 50% weight bearing for the second week. During the first postoperative week, they underwent the same rehabilitation regimen as the aggressive group. All patients performed a standard postoperative physical therapy protocol, and compliance was tracked through weekly logbook entry.

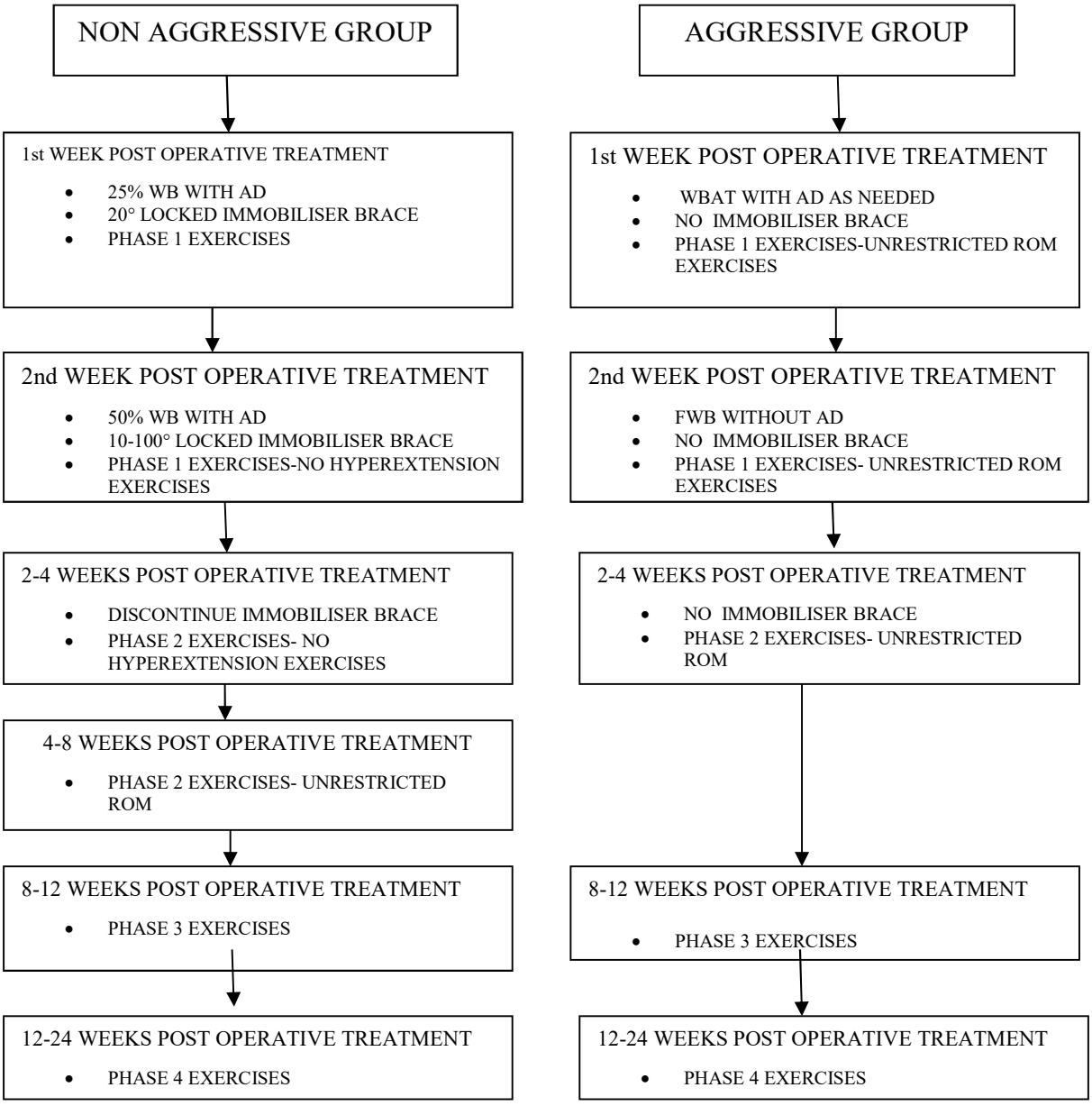

Figure 1:- Treatment protocol for each group. Abbreviations: WB, weight-bearing; AD, assistive device; CPMM, continued passive-motion machine; ROM, range-of-motion; WBAT, weight-bearing as tolerated; FWB, full weight-bearing.

Exceptions to the protocol for the nonaggressive group were as follows: They were confined to a postoperative brace for 4 weeks and not allowed to perform any

hyperextension exercises for the first 6 weeks, and they were instructed to ambulate with a modified weight-bearing status for the first 2 weeks.

Standard post-operative physiotherapy protocol for both groups was as follows:-

•Phase I (0–4 wk) of the rehabilitation protocol included passive, active-assist, and active ROM exercises; stationary bicycling; muscle-activation exercises; and inflammation reduction.

•Phase II (4–8 wk) of the protocol emphasized progressive ROM exercises, muscle strengthening, neuromuscular-control training, and functional activities.

•Phase III (8–12 wk) of the protocol consisted of restoring full symmetrical passive ROM, increased muscle strengthening, higher level neuromuscular-control tasks, and running.

•Phase IV (12–24 wk) of the protocol involved progressive muscle strengthening, sport-specific neuromuscular-control training, plyometrics, sprinting, and cutting drills.

Patients were scheduled for the same number of physical therapy visits and established time periods for exercise progression.

Outcome Measures

The primary outcomes was subjective IKDC scores at 12 weeks, 24 weeks and 1 year. The secondary outcomes were the difference in ROM at the same duration.

The IKDC Subjective Knee Form was used to assess the patient's opinion about his or her knee function and possible associated problems.19 The IKDC is based on a 0-to-100 cardinal scale and a knee-specific subjective measure of symptoms, function, and sport activity.19 The IKDC has been shown to be a reliable and valid instrument in measuring patient-oriented clinical outcomes in daily and sport function.15,19 A dual-arm goniometer was used to measure knee flexion and -extension ROM in both knees, which has shown high reliability.20 The mobility of the knee was measured as described by Shelbourne et al.21 Knee extension was measured with the patient's heel positioned on a bolster to allow the examiner to measure the amount of extension, or hyperextension if present, with the patient in a seated position. Knee flexion was measured by instructing the patient to bend the affected knee as far as possible toward the buttocks in a seated position. The outcome score used for analysis was expressed as the difference in ROM between the surgical and nonsurgical knees for both flexion and extension.

Statistical Analysis

Group 1 was defined as patients undergoing the standard rehabilitation protocol or the non-aggressive group, while group 2 was defined as patients undergoing aggressive rehabilitation. The data was initially captured in the customized proforma designed for the study. Then the data from this customized proforma was entered into the Microsoft Excel for analysis and online software were used for calculating the statistical significant. Unpaired 't' test was used to compare the difference of mean between the two groups, Pearson chi-square of 2x2 was used to compare the two groups. A p value of < 0.05 was taken as statistically significant. The final data was presented in the form of tables and graphs

Results

Seventy patients were enrolled in the study from June 2015 to August 2017. 56 men and 19 women initially met the inclusion criteria for the study. Four men and one woman were later excluded after operative findings indicated the need for meniscal repair. Thus, 70 subjects underwent randomization and began the postoperative rehabilitation protocol. 35 patients each were randomized to the aggressive and

nonaggressive group respectively. Baseline characteristics were not different between groups. No subject was lost to follow-up.

Table No. 1
Distribution of patients according to age in the partial weight bearing and full weight bearing groups

(N=70)

Age Group	Partial Weight Bearing (n=35)		Full Weight Bearing (n=35)	
	No.	%	No.	%
16-20 years	4	11.4	6	17.1
21-30 years	11	31.4	18	51.4
31-40 years	20	57.1	11	31.4
Total	35	100.0	35	100.0
Mean ± SD (age, years)	30.00 ± 6.01		27.77 ± 5.98	
't' value, df	1.555, df=68			
P value	0.125, NS			

Unpaired 't' test applied. P value < 0.05was taken as statistically significant

The above table shows the distribution of patients according to age in both the partial weight bearing and full weight bearing groups.

Table No. 2
Distribution of patients according to gender in the partial weight bearing and full weight bearing groups

(N=70)

Gender	Partial Weight Bearing (n=35)		Full Weight Bearing (n=35)	
	No.	%	No.	%
Female	9	25.7	7	20.0
Male	26	74.3	28	80.0
Total	35	100.0	35	100.0

$\chi 2$ test applied (2x2). $\chi 2$ value = 0.324, df=1, P value = 0.569, Not significant

Table No. 3

Comparison of mean ROM at different time intervals between the partial weight bearing and full weight bearing groups

Parameter	Time Interval	Group	Mean ± SD	't' value	P value
ROM	4 weeks	Partial weight bearing	78.23 ± 10.42	-6.877, df=68	0.000*
		Full weight bearing	93.57 ± 8.09		
	3 months	Partial weight bearing	97.89 ± 11.14	-9.629, df=68	0.000*
		Full weight bearing	121.00 ± 8.81		
	6 months	Partial weight bearing	118.86 ± 10.00	-4.186, df=68	0.000*
		Full weight bearing	127.06 ± 5.85		
	1 year	Partial weight bearing	130.63 ± 6.15	-9.573, df=68	0.000*
		Full weight bearing	141.43 ± 2.59		

Unpaired 't' test applied. P value < 0.05was taken as statistically significant

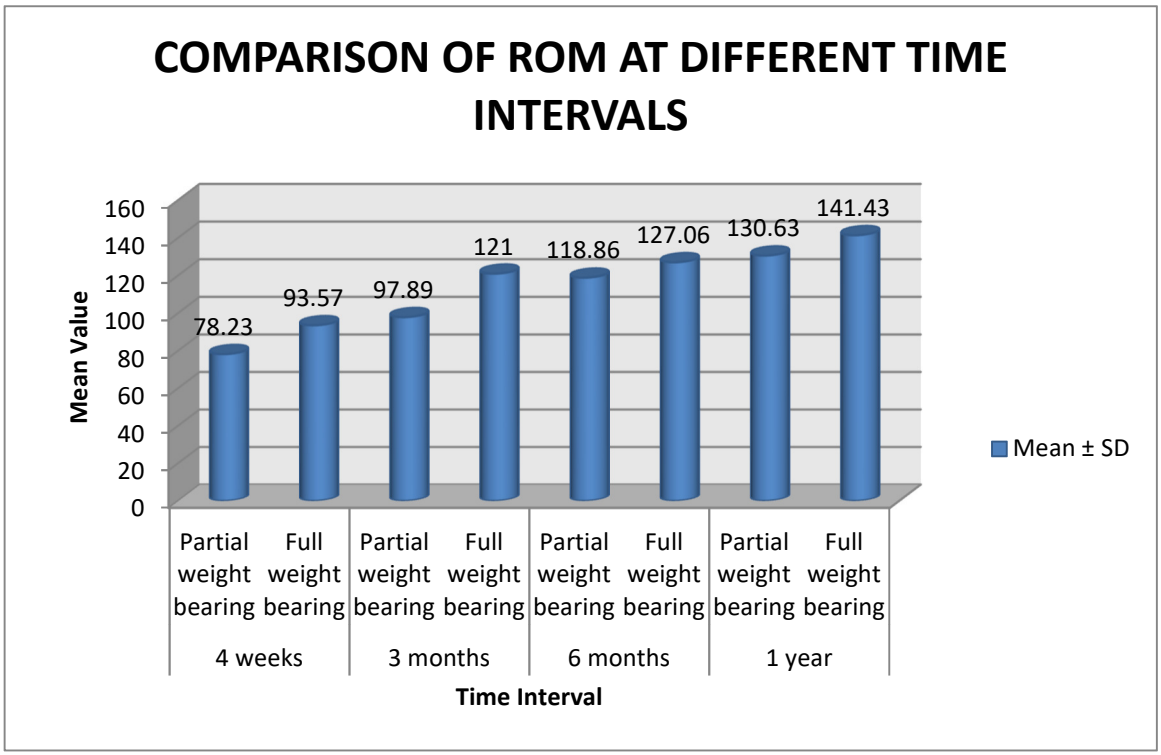

Fig.. : Bar diagram showing comparison of ROM at different time intervals between the partial weight bearing and full weight bearing groups

Table No. 4
Comparison of mean FFD at different time intervals between the partial weight bearing and full weight bearing groups

Parameter	Time Interval	Group	Mean ± SD	't' value	P value
FFD	4 weeks	Partial weight bearing	3.43 ± 3.16	6.704, df=68	0.000*
		Full weight bearing	1.26 ± 2.67		
	3 months	Partial weight bearing	1.11 ± 1.99	0.550, df=68	0.584, NS
		Full weight bearing	0.86 ± 1.91		
	6 months	Partial weight bearing	0.94 ± 1.85	2.112, df=68	0.038*
		Full weight bearing	0.23 ± 0.77		
	1 year	Partial weight bearing	0.37 ± 0.94	2.333, df=68	0.023*
		Full weight bearing	0.00 ± 0.00		

Unpaired 't' test applied. P value < 0.05was taken as statistically significant

The above table shows the comparison of mean FFD at different time intervals between the two groups.

Table No. 5
Comparison of mean 'Difference from Opposite Knee' at different time intervals between the partial weight bearing and full weight bearing groups

Parameter	Time Interval	Group	Mean ± SD	't' value	P value
Difference from opposite knee	4 weeks	Partial weight bearing	-58.91 ± 9.66	-5.861, df=68	0.000*
		Full weight bearing	-46.43 ± 8.09		
	3 months	Partial weight bearing	-39.26 ± 10.24	-8.871, df=68	0.000*
		Full weight bearing	-19.00 ± 8.81		
	6 months	Partial weight bearing	-18.29 ± 9.07	-2.929, df=68	0.005*
		Full weight bearing	-12.94 ± 5.85		
	1 year	Partial weight bearing	-6.51 ± 6.29	-6.908, df=68	0.000*
		Full weight bearing	1.43 ± 2.59		

Unpaired 't' test applied. P value < 0.05was taken as statistically significant

The above table shows the comparison of mean 'difference from opposite knee' at different time intervals between the two groups.

Table No. 6
Comparison of mean IKDC Score at different time intervals between the partial weight bearing and full weight bearing groups

Parameter	Time Interval	Group	Mean ± SD	't' value	P value
IKDC Score	4 weeks	Partial weight bearing	30.02 ± 2.80	-8.318, df=68	0.000*
		Full weight bearing	34.68 ± 1.77		
	3 months	Partial weight bearing	51.98 ± 1.54	-66.018, df=68	0.000*
		Full weight bearing	72.27 ± 0.97		
	6 months	Partial weight bearing	80.50 ± 0.00	0.960, df=68	0.340, NS
		Full weight bearing	79.84 ± 4.07		
	1 year	Partial weight bearing	88.43 ± 4.06	-8.917, df=68	0.000*
		Full weight bearing	96.11 ± 3.09		

Unpaired 't' test applied. P value < 0.05was taken as statistically significant

Overall, we found better results in group 2 (full weight bearing) as compared to group 2 (partial weight bearing) in terms of IKDC scoring, range of motion (ROM), ROM difference from opposite knee and fixed flexion deformity. The results were statistically significant.

Adverse events relative to motion limitations were present in both groups. Three patients (aggressive group n = 2 and nonaggressive group n = 1) required additional visits due to motion limitations, which were deemed necessary by the treating orthopedic surgeon. No other complication was noted.

Discussion

This randomized clinical trial evaluated the effects of early aggressive rehabilitation on patients recovering from ACL-R using STG autograft, while observing the relationship between clinical measures that are paramount in determining a successful outcome. Early aggressive rehabilitation compared with nonaggressive rehabilitation was found to be significantly better in this cohort of patients in relation to primary outcomes of subjective IKDC scores.

Subjects in the aggressive group did demonstrate a significant difference in ROM compared with the nonaggressive group. Our findings support the current body of literature as it pertains to BPTB grafts. Previous studies have compared the effects of early aggressive rehabilitation protocols on outcomes after ACL-R using BPTB grafts, indicating it to be appropriate to proceed through postoperative management without immobilizing the knee, restricting early hyperextension motion, or delaying weight bearing [9,14,15,21].

The primary goal after ACL-R is to restore knee stability and function in preparation for patients to return to their previous level of activity. However, even with advancements

in surgical techniques and rehabilitation protocols, there is strong evidence that deficits in lower extremity strength, neuromuscular control, and proprioception are continually present as patients are released back to unrestricted sport function[22,23]. Paterno et al reported that female athletes who had been cleared for full unrestricted sport activity still present with significant landing and jumping asymmetry during a vertical drop-jump task that has been used to predict ACL injury risk [24]. This evidence demonstrates that higher-level rehabilitation methods need to be emphasized in later stages of recovery after ACL-R in hopes of reducing the residual limb asymmetries and potentially decreasing the risk of future re injury. Furthermore, future research is needed to establish an objective criterion based on functional testing and outcomes before returning patients back to unrestricted sport after rehabilitation.

Early aggressive rehabilitation has been established for years, but there are discrepancies in the literature relative to overemphasis on BPTB grafts and lack of postoperative management on STG grafts. Our findings are clinically relevant since STG autografts have gained popularity in comparison with other graft choices, and limited research has been conducted evaluating the effects of early aggressive rehabilitation on functional outcomes. This evidence is important for guiding clinicians in making appropriate decisions on postoperative rehabilitation and restrictions after surgery, because there still appears to be conflicting evidence [14]. The current study appears to indicate that an early aggressive postoperative protocol is superior to a nonaggressive rehabilitation protocol after an isolated ACL-R using STG autograft.

The current study had certain limitations. First, outcomes like A-P knee laxity were not gathered. Second, no independent blinded data collector was used in this study, leading to potential performance bias. Third, our small sample size was small and composed of active subjects, and we were unable to stratify groups by activity level.

Conclusion

We found early aggressive rehabilitation to be superior to nonaggressive rehabilitation after isolated ACL-R using STG autograft for the primary outcomes of knee ROM, FFD and subjective IKDC score. The study emphasizes that early aggressive rehabilitation in such cases is better at restoring the normal function of knee when evaluated objectively as well as subjectively.

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