



POST-OPERATIVE STABILIZING KNEE FOOT ORTHOSIS VS. NO ORTHOTIC INTERVENTION AFTER KNEE LIGAMENT RECONSTRUCTION: IMPACT ON STABILITY AND REHABILITATION. A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Postoperative knee bracing is traditionally used after anterior cruciate ligament reconstruction (ACLR) to protect the graft by limiting excessive knee motion. However, evidence regarding its efficacy in enhancing stability and functional recovery remains conflicting.

Objective: To compare postoperative stabilizing knee foot orthosis versus no orthotic intervention on knee stability, function, and rehabilitation outcomes after ACLR.

Methods: In this randomized controlled trial, 86 patients undergoing bone-patellar tendon-bone ACLR were allocated to a braced group (n=43) or a non-braced group (n=43). Both groups followed a standardized rehabilitation program for six months. Outcomes included instrumented laxity, isokinetic muscle strength, one-leg hop test, range of motion (ROM), knee circumference, Lysholm score, Tegner activity score, and visual analogue scale (VAS) for pain/instability. Data were collected preoperatively and at 3- and 6-month follow-ups.

Results: No significant differences were observed between groups for knee laxity, ROM, isokinetic torque, or hop performance ($p>0.05$). The non-braced group demonstrated smaller knee circumference at 3 months and higher Tegner activity scores at 3 and 6 months ($p<0.01$). Both groups achieved excellent Lysholm scores (>90) and low VAS scores

by 6 months, with no intergroup differences.

Conclusion: Postoperative bracing after ACLR did not provide superior stability, pain control, or functional outcomes compared with no orthotic intervention. These findings suggest that routine use of postoperative knee braces may not be necessary, allowing simplified rehabilitation without compromising patient outcomes.

Introduction

Anterior cruciate ligament (ACL) injuries are among the most prevalent knee pathologies in athletes and physically active individuals, often resulting in instability, reduced function, and an increased risk of long-term complications such as early osteoarthritis (1,2). The ACL is essential for restraining anterior tibial translation and controlling rotational stability, making it a critical structure for functional performance in dynamic activities such as cutting, pivoting, and jumping (3). Epidemiological studies report a steadily rising incidence of ACL injuries, attributed to increased participation in competitive sports and recreational activities (4). Consequently, ACL reconstruction (ACLR) has become a widely performed surgical procedure aimed at restoring stability and function (5). Postoperative management following ACLR is a matter of ongoing debate, particularly regarding the use of external orthoses such as stabilizing knee braces. Traditionally, knee braces have been prescribed to protect the graft, limiting harmful movements, and providing psychological security during early rehabilitation (6,7). These orthoses are generally categorized into prophylactic, rehabilitative, and functional types, each designed with specific objectives such as injury prevention, controlled mobilization, or return to sport (8). In the context of ACLR, rehabilitative braces are most frequently employed, typically worn for 4–6 weeks postoperatively with adjustable hinges to restrict range of motion (9).

Despite their widespread use, the actual clinical benefit of postoperative knee bracing remains controversial. Proponents argue that bracing enhances joint stability, reduces anterior tibial translation, and limits varus-valgus stresses, thereby protecting the graft during its vulnerable early healing phase (10,11). Biomechanical investigations demonstrate that braces may reduce anterior tibial displacement under applied loads, suggesting a potential role in reducing reinjury risk (12). Additionally, some studies emphasize the psychological benefit, as patients may feel more secure and confident performing activities when wearing a brace (13). Conversely, a growing body of evidence challenges the necessity of postoperative bracing. Critics argue that braces are unable to replicate the knee's natural six degrees of freedom and may even hinder recovery by restricting range of motion, increasing joint swelling, or contributing to muscle fatigue (14,15). Randomized controlled trials (RCTs) have consistently reported no significant differences in knee stability, functional performance, or long-term outcomes between braced and non-braced groups after ACLR (16,17). Moreover, concerns regarding increased rehabilitation costs, reduced patient compliance, and potential delays in regaining full mobility have further fueled skepticism regarding routine brace use (18,19).

Beynon et al.'s study of functional braces found that three of the seven braces had a larger protective strain-shielding effect on the anteromedial bundle of the ACL than did the brace alone when an internal torque of 5 Nm was applied about the long axis of the tibia. When a 180 N anterior shear load was given to the knee in 30° of flexion, none of the functional braces examined showed any discernible strain-shielding. With an applied anterior shear stress of 100 N, two of the braces the Townsend knee brace from Townsend Industries in Bakersfield, California,

and the DonJoy 4-point Sport ACL brace with ACL accessory strap from DonJoy in Carlsbad, California, respectively provided a strain-shielding effect on the ACL.(20) None of the braces had any impact on ACL strain during active ROM of the knee from 10° to 120° or during quadriceps isometric contraction. Noyes et al., hypothesized that during daily activities, the ACL is exposed to stresses ranging from 0-454 N in an effort to reduce consequences following surgery, including stiffness, weakness, and patellofemoral issues. (21) Based on their observations of patients' progress, Shelbourne et al. (22) created a more expedited rehabilitation program. Given that animal studies have shown that the patellar tendon ACL graft revascularizes, weakens, and heals, one may be concerned that stressing the graft would cause straining or graft failure. In a long-term follow-up (2–6 years), Shelbourne et al. (23) discovered that an expedited rehabilitation program has no impact on the graft's long-term stability. Recent meta-analyses and systematic reviews reinforce these findings, concluding that postoperative bracing neither reduces graft failure nor improves subjective or objective outcomes compared with no bracing (25). Nonetheless, variability in patient populations, surgical techniques, and rehabilitation approaches makes it difficult to establish definitive recommendations.

Given this background, the present study aimed to evaluate the effectiveness of postoperative stabilizing knee foot orthosis compared with no orthotic intervention in patients undergoing ACLR. Specifically, we sought to determine the impact on joint stability, functional recovery, pain, and rehabilitation progress over six months. We hypothesized that postoperative bracing would not provide significant advantages over a non-braced rehabilitation protocol. This study addresses an important gap in the literature by directly comparing postoperative outcomes in patients with and without bracing using a randomized controlled trial design. Findings from this trial will contribute to ongoing discussions regarding the necessity of routine bracing in postoperative ACL rehabilitation and may guide clinicians in adopting evidence-based practices that balance effectiveness, patient comfort, and healthcare costs.

Methodology

This randomized controlled trial was conducted at Reman Medical Institute, Peshawar. following approval from the Institutional Research Ethics Board, a randomized controlled trial (RCT) with two parallel groups to compare the effectiveness of a post-operative stabilizing knee-foot orthosis (KFO) versus no orthotic intervention in patients undergoing knee ligament reconstruction. The study adhered to the CONSORT guidelines for reporting randomized trials to ensure methodological rigor and transparency. The study was carried out at the Department of Orthopedic Surgery and Physiotherapy and Rehabilitation, Rehman Medical Institute, Peshawar. All participants were recruited from outpatient and inpatient orthopedic clinics of the same institution.

Sample size was calculated with the assumption that 30% patients after ACLR face knee instability. Confidence interval was kept 95% and according to Fleiss and CC method 86 sample size was calculated. Total 86 individuals with unilateral ACL injuries were scheduled for ACL repair in this randomized research. Patients with related meniscal injuries were included in the research while patients with injuries to the posterior cruciate, medial collateral, or lateral collateral ligaments were excluded. After receiving informed permission, the patients were randomized to either group A (n = 43) who did not receive any orthotic support or group B (n = 43), which received treatment with a rehabilitative knee brace for 6 weeks following surgery. The identity of the patient's group was hidden from the doctors. The non-braced group's median time from injury to surgery was 10 months, compared to the braced group's median duration of 6 months. Group A had 20 women and 23 men, whereas Group B contained 17 women and 26

men. In group A, the median age was 35, whereas in group B, it was 26. There were two lateral and five medial meniscus injuries in group A. Four medial and three lateral meniscal injuries were found in group B. No tears were stitched, but all meniscus injuries were managed arthroscopically.

Procedure of Surgery:

Seven surgeons participated in the trial. Four people used the endoscopic method described by Rosenberg (10) to accomplish an arthroscopic ACL restoration utilizing a patellar tendon autograft and fixation with interference screws. In a modified procedure, the other three surgeons (11) drilled the femoral tunnel from the outside, using the rear entrance guide, and fixed the patient with interference screws. According to the literature, these two methods produce the same stability.

Test of Laxity:

According to Andersson and Gillquist's description, the instrumented laxity test was conducted at 20° flexion (90 N). Starting with posterior laxity, the test was continued until the acquired result stabilized. Measurements were taken prior to surgery as well as three and six months thereafter. (12)

Evaluation of functional performance:

Using a Kintrex 1000, isokinetic peak extension/flexion torque was recorded at angular velocities of 90° and 180°/s. To become used to the equipment, the patients performed five submaximal repeats. The peak torque was then collected from one of three maximum repetitions. Calculated was a ratio between the damaged and unaffected leg. Measurements were taken prior to surgery as well as three and six months thereafter. Three months and six months following surgery, the one-leg-hop test was carried out.(13) In order to accomplish this, the patient must leap off with one leg and land on that same leg without losing balance or shifting to the other. The patients repeat the hop if they lose their equilibrium. The arms were left free during the test. Each leg's longest of three jumps was measured in centimeters, beginning with the side that wasn't involved. Calculated was the ratio of the damaged to uninjured limb.

Range of Motion:

The patient was placed in the supine position while the active ROM was assessed using a long-armed goniometer. Measurements were taken before to surgery, three months afterwards, and six months thereafter. To minimize the impact of soft tissue and reflect knee swelling, the circumference of the knee joint was measured in the center of the patella. Measurements were taken three times until they produced the same result, at which point they were compared to the unaffected leg. Prior to the procedure as well as six and twelve months thereafter, measurements were taken.

Knee Function Assessment:

The Lysholm score was used to evaluate knee function.(14) Measurements were taken before surgery as well as three and six months thereafter. The Tegner activity score was used to assess activity level.(15) Prior to the procedure, 3 months and 6 months after procedure, measurements were taken. The patient's subjective perception of daily pain, discomfort, and instability was measured using a visual analogue scale (VAS), rated 0–10. Prior to surgery as well as three and six months afterwards, the VAS measurement was carried out.(16)

Analysis:

We employed the Mann-Whitney U test for the nonparametric assessments of VAS, Lysholms score, and Tegner activity level score. An analysis of variance for repeated measures was used to the parametric measurements of ROM, laxity, isokinetic peak torque, knee circumference, and

the one-leg hopping test. The T test was used to compare groups' differences in age and the interval between the injury and operation. Statistical significance was defined as a P value of less than 0.01.

Post-surgery Rehabilitation:

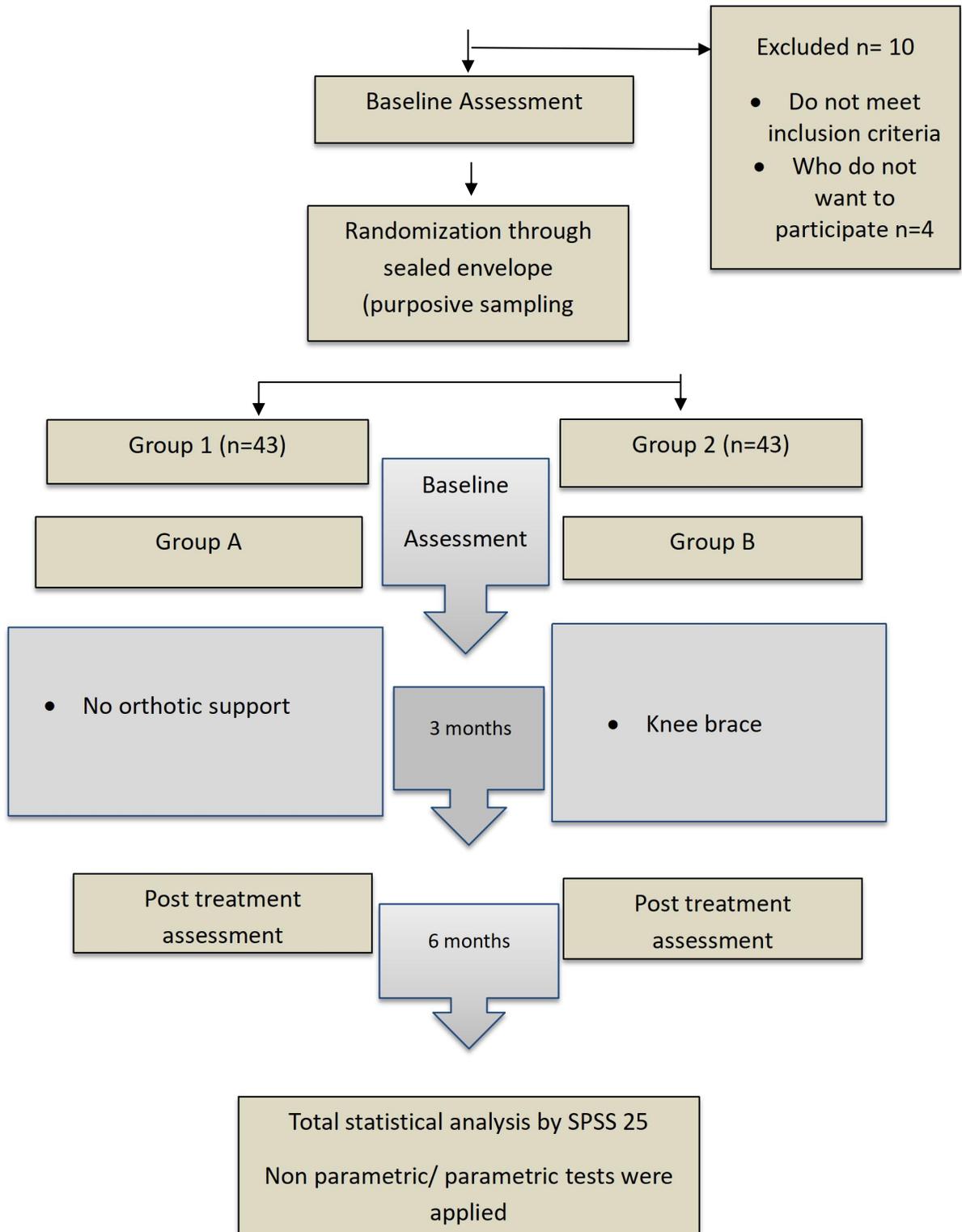
Following a typical approach that included early weight bearing, both groups underwent rehabilitation. In contrast to those in group B, patients in group A were treated without the use of a postoperative rehabilitation brace for 6 weeks following surgery 2 weeks throughout the day and night and 4 weeks just during the day. While supporting weight, the brace was fully extended and secured in place. The patient was given full range of motion while not bearing weight. When we encountered patients in group B for follow-up, we asked them to confirm that they wore the brace as directed, and every patient said they did.

Duration	Rehabilitation
1-2 Days	Knee extension to 0 degrees, ankle pump, cold compression (AirCast), and active aided flexion. Leg control workouts using isometrics. Toe lifts and weight changes
2 days – 6 weeks	Brace removal for exercise (twice daily), mobilization of the patella, Active ROM exercises were continued, with aided ROM 110° at 4 weeks. Bicycling, Raises of the straight leg in four planes, raising calves, Weight changes and miniature squats, curled-up hamstrings, practice with proprioception
6-7 weeks	Complete extension while active, knee extension (90–45 degrees), hip abduction, and Starting a swimming program, stretching, Continue all of the aforementioned exercises, with a focus on the close-kinetic-chain workouts.
8-11 weeks	Squats, lateral step up, squats
3-4 months	Keep up the assisted ROM workouts, 90° of knee extension start a mild exercise program, start a plyometric training program, Individualized sport-specific instruction and exercises that are catered to each patient's abilities, attained symmetrical aided ROM, Regular stride and ongoing, accelerated muscular training.
5-6 months	Continue your plyometric training, close-kinetic chain training, all-around strengthening program, and running and agility training.
6 months	The one-leg-hop test and isokinetic testing are carried out. Before resuming to full activity, the contralateral knee should be 90% strong, performing, and have an acceptable clinical assessment.

RESULTS:

Between 25 Feb 2022 to 5 Sept 2023, total 100 surgical candidates were approached for the purpose of this clinical trial, 10 candidates were not fulfilling the criteria of inclusion, 4 candidates refused to take part in the study and remaining 86 candidates were randomized into two group.

Assessed for eligibility n=100



Laxity:

Between the groups, there was no significant change in knee laxity. In both groups after ACLR and rehabilitation there was considerable increase in stability following surgery. (P value=0.445)

Table 2. Laxity measurements

	No brace n=43	Knee Brace n=43	P value
Baseline	4.3±1.7	4.0±2.4	0.455
3 months	1.5±1.8	1.4±1.6	
6 months	2.7±1.3	1.3±1.7	
*Repeated ANOVA			

Functional Performance:

Before surgery, 3 months after surgery, or 6 months after surgery, there were no differences between groups A and B in the ratio of the damaged to the uninjured side at any of the velocities for concentric flexion or extension peak torque. Three months and six months following surgery, there was no change in the groups' scores on the one-leg-hop test.

Table 3. Functional performance

	No brace n=43	Knee Brace n=43	P value
Quads peak Ext torque			
90 degree			0.002
Baseline	77±23	82±21	
3 months	75±11	71±12	
6 months	95±14	91±16	
180 degree			0.062
Baseline	86±21	89±21	
3 months	79±11	75±12	
6 months	91± 10	87±14	
Hams peak Flex torque			
90 degree			0.223
Baseline	90±26	104±19	
3 months	107±17	103±16	
6 months	100±9	105±14	
180 degree			0.555
Baseline	90±29	102±20	
3 months	103±21	101±19	
6 months	100±13	102±14	
One leg Hope test			0.332
3 months	80±11	84±15	
6 months	90± 9	96±13	
*Repeated ANOVA			

Range of Motion:

After three and six months, we discovered no appreciable variations in ROM across the groups.

Table 4. ROM

	No brace n=43	Knee Brace n=43	P value
ROM Ext			0.113
Baseline	-1±6*	-1±6*	
3 months	0±4*	0±4*	
6 months	-1±2*	-1±2*	
ROM Flex			

Baseline	139±9	143±10	0.022
3 months	137±11	135±12	
6 months	142±9	140±6	
Circumference (cm)			0.004
Baseline	0.7±0.4	0.6±0.3	
3 months	1.2 ±0.8	1.3±0.9	
6 months	0.3±0.5	0.5±0.7	
Repeated ANOVA			
*Hyperextension			

Knee Function:

After 3 months, there was a substantial difference in favor of group A according to the Tegner activity score (P=0.001). Table 5 shows that group A's median score was 5 (0-7) while group B's was 4 (0-7). Two years after surgery, there was no difference between the groups. There was no discernible difference between the groups based on the VAS evaluation or the Lysholm knee score (Table 5). As early as 3 months following the procedure, patients in both groups achieved very high Lysholm functional scores. Group A earned an 82, while Group B earned an 81. This suggests that at this point, no group was experiencing any significant issues. This is further supported by the low median VAS score at the 6 month follow-up (Table 5).

Table 5. Knee Function

	No brace n=43 Median (Range)	Knee Brace n=43 Median (Range)	P value
Lysholm Score			
Baseline	75 (46–99)	75 (41–98)	0.233
3 months	82 (50–97)	81 (30–99)	0.433
6 months	96 (75–99)	93 (59–100)	0.677
Tegner Score			
Baseline	3 (1–6)	3 (0–7)	0.551
3 months	5 (0–7)	4 (0–7)	0.001
6 months	7 (0–8)	6 (0–10)	0.006
VAS pain			
Baseline	0.8 (0–6.7)	1.2 (0–6.5)	0.322
3 months	0.9 (0–5.5)	0.5 (0–8.5)	0.224
6 months	0.5 (0–4.6)	0.1 (0–3.5)	0.122
VAS Instability			
Baseline	3 (1–9)	6 (0–8.9)	0.112
3 months	0.7 (0–8.2)	1.3 (0–6.5)	0.334
6 months	0.3 (0–5.8)	0.2 (0–5.5)	0.116

DISCUSSION:

After an ACL repair, a rehabilitative postoperative knee brace is worn to avoid knee stresses caused by varus-valgus motion and to restrict extension and flexion motions. According to our clinical observations, postoperative knee braces compress the leg's soft tissues and exacerbate postoperative edoema. The brace is bulky and unpleasant to wear for many individuals. Due to the external compression used, Styf et al. (26) shown that a functioning knee brace causes more early muscle fatigue than an unbraced limb. Additionally, they claimed that it causes a drop in

the local blood perfusion pressure in the braced leg and an increase in muscle relaxation pressure during exercise. This may help to explain why the group without a brace had smaller knee circumferences.

We are aware of the difficulties in precisely estimating the swelling's degree. Despite this, we believe that the technique we utilized, which involves measuring at around the middle patella level and avoiding as much soft tissue as possible, provides a reasonably accurate representation of the swelling in the knee joint. Eight commercially available rehabilitative knee braces were the subject of a biomechanical analysis by Cawley et al. (27), who discovered that most of the braces considerably reduced both translation and rotation when compared to the unbraced limb. The stresses employed in this experiment were well below physiological levels, and it was conducted under static test settings. By dramatically lowering the strain values for the knee in both weight-bearing and non-weight-bearing settings with anterior directed loading of the tibia up to 140 N, Genty et al. (28) showed that functional knee bracing had a preventive impact on the ACL. By considerably lowering strain values in response to tibial internal and external torques of up to 6 Nm (using a torque boot strapped to the subject's foot), the bracing also had a protective impact on the ACL when the knee was not bearing weight.

It's possible that bracing has different effects in different knee positions because all tests in this inquiry were conducted with the knee in a 30° flexion position. In the research by Harilainen et al.(20), there were no discernible changes between patients who had bone-patellar tendon-bone ACL restoration and those who did not wear a brace. Only the outcomes 1 and 2 years after surgery were described; no information was provided on the early postoperative rehabilitation phase. Knee edoema, range of motion, or any functional assessments like the one-leg hopping test are not evaluated in the research. In a research that included 78 consecutive patients and a 2-year follow-up, Kartus et al. came to the same findings.(29)

All patients were assessed before to surgery and a prospective, randomized approach was adopted. We often performed controls on our patients and observed disparities between the groups over the postoperative period. Three months following surgery, the knee circumference was smaller in the non-braced group's favor, indicating less knee swelling. Six months following surgery, the non-braced group had a considerably greater level of activity than the braced group. This would suggest a quicker recovery in group A from the beginning up to six months. There was a numerical difference in laxity, indicating that there was an average laxity difference between the groups following surgery. In a research utilizing a canine model, Beynnon et al. (30) hypothesized that excessive tension placed on the graft during the healing phase may contribute to increased anterior knee laxity. However, there was no statistically significant difference in knee stability between the braced and unbraced groups, and this difference was not substantiated by any other findings.

At 3 and 6 months, we found no difference between the groups in the patients' subjective VAS scores for pain and daily life insecurity. This shows that the patient's daily activities are unaffected by whether he is wearing a brace or not. This conclusion may be supported by the fact that we discovered no differences between the groups when comparing the Lysholm functional score 12 weeks following surgery. We concluded that this knee brace had no positive effects on subjective or objective knee function after 6 months following surgery.

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