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TO BRACE OR NOT TO BRACE? EARLY POSTOPERATIVE OUTCOME AFTER ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING A HAMSTRING GRAFT: A RANDOMIZED PROSPECTIVE STUDY

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ABSTRACT

The aim of this study is to compare the clinical outcomes of a consecutive series of 186 patients having been treated for anterior cruciate ligament reconstruction with a hamstring graft in whom a brace was used or not in the early postoperative period. A randomized prospective study of athletes undergoing anterior cruciate ligament reconstruction using the same surgical technique and the same graft (hamstring) was carried out. Three different groups were investigated: no brace, rigid brace in full extension (for 4 weeks), or articulated brace (0-90° for first 3 weeks then 0-120° for another week). All patients were assessed preoperatively and at follow-up for thigh muscle atrophy, range of motion, pain, quality of life, and subjective scores (Lysholm-Tegner score, IKDC score). Rehabilitation started at 2.2 ± 1.3 days after surgery. All of the athletes followed the same postoperative rehabilitation protocol with progressive daily sessions that ended 24 weeks after surgery. No significant differences were found concerning the use of a brace in early postoperative rehabilitation. At the final follow-up (24 weeks after surgery), side-to-side differences in laxity (as measured by KT-1000 arthrometer) between the involved and not-involved leg were 2.2±1.6 mm for NB (no-brace) group, 2.1±1.2 mm for AB (articulated brace) group and 2.3±1.3 mm for RB (rigid brace) group. There were no significative post-operative side-to-side differences in knee circumference between the three groups at 24 weeks follow-up (0.3±0.2 cm in the NB group, 0.2±0.2 cm in the AB group, and 0.1±0.4 cm in the RB group, respectively*)*. Post-operative IKDC scores were 86.2±6 in the NB group, 82±12.6 in the AB group, and 81.6±13.2 in the RB group respectively. There was no significative difference in terms of ROM between the three groups at 6, 12, and 24 weeks and similar functional improvement as measured by Lysholm-Tegner activity score at the final follow-up. The present study did not show any difference in the rate of complications or residual laxity and clinical outcomes among the three groups. According to these data, postoperative bracing after anterior cruciate ligament reconstruction did not show any advantage and cannot be recommended.

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INTRODUCTION

The anterior cruciate ligament (ACL) tear is a common injury, mainly occurring in young and active athletes during sports that involve sudden stops with changes in direction or pivoting, such as soccer, basketball, or volleyball (1).

ACL tears account for 25 to 50% of all ligamentous knee injuries and are usually combined with other injuries, typically to menisci, cartilage, and/or collateral ligaments (2). The poor healing capacity of the ACL is one of the main reasons why the operative approach is currently the gold standard in athletes with ACL injuries (3).

ACL injuries were probably described for the first time by the Ancient Greeks (4) but the first attempt at ACL repair was described by Mayo Robson in 1895 using catgut ligatures (5). Primary ACL repair quickly became the gold standard for ACL lesions in the 1970s and 1980s (6-9). However, in the following years, several randomized controlled trials showed improved outcomes with reconstruction compared to primary repair. Therefore, from the beginning of the 1990s, open ACL repair was replaced by ACL reconstruction. Nowadays, between 60000 and 175000 ACL reconstruction procedures are performed each year in the United States (10). Several grafts have been proposed, including autografts (bone-patellar-bone, hamstrings, and quadriceps tendon), allografts, and synthetic grafts.

The rehabilitation protocols have significantly changed in parallel with the evolution of surgical techniques and fixation devices. In the last decades, there has been a general trend toward early mobilization and accelerated protocols with the final goal of returning to pre-injury activity at a high functional level as quickly as possible. However, rehabilitation must be effective and safe at the same time, and a real consensus on which is the most effective rehabilitation protocol is still missing, especially in patients with associated injuries (11). Post-operative immobilization with brace or other devices is one of the most discussed aspects. Knee bracing is used in up to 85% of patients to protect the repair and to prevent retears by reducing mechanical loads (12).

The type of bracing and the duration of its use are highly variable in literature with no unique protocol. Although the majority of surgeons are in favor of the use of a post-operative brace after ACL reconstruction, there is no scientific evidence to support its routine use. Postoperative bracing does not seem to be advantageous in terms of pain relief, stability, function, and rehabilitation (13-15). The present study aimed to compare the outcomes and complications associated with using an articulated brace, a rigid brace, or no brace in patients undergoing ACL reconstruction with a hamstring autograft.

MATERIALS AND METHODS

The present study was designed as a randomized prospective study according to the ethical recommendations of the Helsinki Declaration. All the enrolled patients were informed and spontaneously gave their own written consent. 186 patients undergoing ACL reconstruction with an autologous hamstring graft (performed by the same experienced surgeon) were randomly divided into three equally distributed groups: no brace (NB), articulated brace (AB), or rigid brace (RB) according to its use or not in the early postoperative rehabilitation period (4 weeks). The three groups were homogeneous in terms of age, gender, and delay between trauma and surgery (Table I).

Table I. *Baseline demographic data.*

	NB	AB	RB
Sex	46 M; 16 F	48 M; 14 F	50 M; 12 F
Involved knee	32 R; 30 L	34 R; 28 L	40 R; 22 L
Mean Age	24 years	26 years	25 years
Height	168 cm	166 cm	166 cm
BMI	22.4 Kg/m^2	24.2 Kg/m^2	24.6 Kg/m^2
Time between trauma and surgery	4.5 months	5.3 months	4.2 months
ROM	5-100°	4-96°	7-104°
Antero-posterior laxity (side-to-side difference)	5.2 ± 2.3 mm	4.9 ± 2.7 mm	5.3 ± 2.6 mm
Lysholm score	66	65	67
Tegner score (before trauma)	7	6	7
Graft diameter	8 mm	9 mm	8 mm

The diagnosis of ACL lesion was taken after clinical evaluation and MRI scan. The ACL reconstruction was performed using the same arthroscopic technique by the same senior surgeon under loco-regional or general anesthesia in all cases. Bone tunnels were performed with dedicated instrumentation in an anteromedial fashion (femur) and standard 55° (tibia). Hamstring tendons were fixed with a suspensory device (Smith & Nephew Endobutton®) on the femur and an absorbable screw (Smith & Nephew Biorci-HA®) on the tibia. Concomitant injuries such as cartilage or meniscus lesions were addressed (and recorded) during the same procedure. Exclusion criteria were meniscal sutures, other ligament reconstruction, skeletally immature patients, and patients with previous surgery on the index knee. Local intra-articular tranexamic acid injection was performed at the end of the surgery, and no closed suction drain was applied. All the patients received the same analgesic protocol (Acetaminophen 1 gr 3 times a day for 5 days) and were dismissed the day after surgery with a tolerance weight-bearing using two crutches.

Patients were included in one of the three groups by a random allocation performed with statistical software (Random Allocation Software v. 1.0 ®). In the NB group, all patients had their knees free of any restriction from the day of the operation and for the following 4 weeks. In the RB group, all patients had a Zimmer-type rigid brace (set at fixed 0° of extension) for the follow-up (FU) period (4 weeks). In the the AB group a DonJoy ® articulated brace was used in all cases (0-90° during the first three weeks, then 0-120° for the following week). The brace was worn upon waking during the early rehabilitation step (4 weeks). Rehabilitation started at 2.2 ± 1.3 days after surgery. All the patients received the same post-operative instructions and complied with the same rehabilitation protocol that ended 24 weeks after surgery (Fig. 1).

Phase I (weeks 0-4)
- Weight-bearing: as tolerated with two crutches
- Range of motion: active range of motion as tolerated (starting 7 days after surgery)
- Non-weight-bearing stretching of the gastrocnemius/soleus
- Straight-leg raise with the knee in full extension
- Electrical stimulation of the quadriceps
- Gluteal isometric and eccentric activation
- No hamstring stretching
- Ice packs for 20-30 minutes at a time

Phase II (weeks 4-6)
- Weight-bearing: as tolerated with two crutches (discontinue crutch use)
- Range of motion: work on progressive knee flexion – maintain full knee extension (prone assisted knee flexion and extension)
- Hamstring stretching and balance exercises
- Closed chain extension exercises
- Exercise bike – start elliptical trainer
- Progress to the weight-bearing stretch of the gastrocnemius/soleus

Phase III (weeks 6-16)
- Full weight-bearing (without crutches)
- Active full range of motion
- Hamstring strengthening
- Continue concentric and eccentric quadriceps, gluteals, and hamstring exercises
- Proprioception activities
- Single-leg drop landing (5 cm)
- Advanced closed-chain strengthening exercises
- Straight-ahead running (at 12 weeks)

Phase IV (weeks 16-24)
- Cutting exercises and sport-specific drills
- Sport-specific cardio training
- Jogging with directional change/uneven surface and with turns 90/180/360°
- Jogging and cutting with a 45° change of direction
- Acceleration and deceleration running
- Program for strength and endurance
- Outdoor cycling
- Return to sport at 5 months

Fig. 1. *Rehabilitation protocol: ACL reconstruction with hamstring autograft.*

Patients were blindly evaluated pre-operatively and post-operatively (at 2, 6, 12, and 24 weeks) by the same orthopedic surgeon using KT-1000 arthrometry, range of motion (ROM) exam, knee circumference, visual analogue scale (VAS), Lysholm score, Tegner activity score, and IKDC score. The same examiner recorded the same measurements at all follow-up evaluations. Passive knee joint stability (anterior displacement of the tibia relative to the femur) was measured and recorded by the same observer using the KT-1000 arthrometer (MEDmetric, San Diego, California) at the manual maximum force. The tests were performed with the patients in a supine position and the knee flexed at 20-30°, recording the difference between involved and not-involved legs. Active ROM was measured using a goniometer with the patient in a supine position, while knee circumference was measured 2 cm proximally to the superior pole of the patella, comparing the results of both legs. All patients received a VAS to evaluate their perceptions of pain and discomfort in daily life. A VAS is a 100-mm long horizontal line with verbal descriptors (word anchors) at each end to express the extremes of the feeling. Patients put a cross on the line at the point that best corresponds to their actual pain (16-18).

Activity level was determined using the Lysholm score and Tegner activity score to document the pre-injury activity level and to compare it with the post-operative level (at 24 weeks follow-up). Lysholm knee scale (first described in 1982) (19) is a patient self-completed questionnaire including 8 items to describe daily living activities (limp, support, locking, instability, pain, swelling, stair climbing, and squatting). The total score is the sum of each response to the 8 items (with a maximum score of 100).

Tegner activity scale is a graduated list of activities of daily living, recreation, and competitive sports (with a score varying from 0 to 10): the patient is asked to select the corresponding activity level (20). Tegner activity scores have been developed to complement the Lysholm scale, based on observations that limitations in function scores (Lysholm) may be masked by a decrease in activity level.

The knee function was assessed using the International Knee Documentation Committee (IKDC) score; it is a 10-item questionnaire made up of three sections with both a subjective part and an objective evaluation form (21-23). The first section assesses symptoms such as swelling, stiffness, pain, locking, and giving way feeling. The second section evaluates daily activities and sport and the third assesses the knee function before and during the injury. The items are added to produce a single index (higher values indicate higher function levels and minor knee symptoms). IKDC can be easily scored using the online scoring sheet.

Statistical analysis

The Mann-Whitney *U* test was used for the nonparametric measurements of the Tegner activity level score and VAS score. An analysis of variance for repeated measurements was used for parametric measurements of knee circumference, ROM, anteroposterior laxity, and IKDC. Analysis of covariance was used to adjust for any initial differences between the groups concerning the following covariates: age, gender, and activity level. Statistical significance was set at $p < 0.05$. All statistical analyses were carried out by an independent statistician and performed with the SAS (Statistical Analysis System) software (SAS Institute, Inc., Cary, North Carolina).

RESULTS

None of the patients was lost at the follow-up, and all completed the outcome measures. There were no significant differences concerning age, gender, activity level, range of motion, instability, and time from injury to operation at time 0 (before surgery) (Table I).

Meniscus injuries were reported in 28 patients in the NB group, 36 patients in the AB group, and 44 patients in the RB group: all these meniscus injuries have been treated with selective meniscectomy (Table II). Six patients developed postoperative complications (Table III).

Table II. *Associated lesions.*

Associated lesion	NB	AB	RB
Meniscus injuries (requiring meniscectomy) n.	28	36	44
Cartilage lesion (I-II Outerbridge grade) n.	24	28	36

Table III. *Post-operative complications.*

	Complication	Delay from surgery (weeks)	Group
1	Early Local infection	<2	NB
2	Early Local infection	<2	RB
3	Extension deficit	8	RB
4	Intraarticular loose body	12	AB
5	ACL re-rupture	20	NB
6	ACL re-rupture	22	AB

These included local infection in 2 patients (adequately treated with prolonged antibiotic therapy for 6 weeks), extension deficit in 1 patient (requiring arthroscopic arthrolysis), intraarticular loose body (requiring arthroscopic removal) in 1 patient, re-rupture of the ACL due to a new trauma during sports activity in 2 patients (requiring a new ACL reconstruction). The average pre-operative side-to-side difference in laxity (as measured by KT-1000 arthrometer) between the involved and non-involved leg was 6.2±2.3 mm in NB group, 5.9±2.7 mm in AB group and 6.3±2.6 mm in RB group respectively. At the final follow-up, the corresponding values were 2.2±1.6 mm for the NB group, 2.1±1.2 mm for the AB group, and 2.3±1.3 mm for the RB group, respectively (Table IV). No statistically significant difference emerged between the 3 groups at each follow-up.

Table IV. *Anterior-posterior laxity (KT-1000 measurements): side-to-side difference measured pre-operatively and at 24 weeks follow-up.*

	Pre-op	Post-op (24 weeks)
NB	6.2 ± 2.3 mm	2.2 ± 1.6 mm
AB	5.9 ± 2.7 mm	2.1 ± 1.2 mm
RB	6.3 ± 2.6 mm	2.3 ± 1.3 mm

There was no significant difference in ROM between the three groups at 6, 12, and 24 weeks. At the last follow-up (24 weeks after surgery) the average extension in NB, AB, and RB groups were -3±1, -2±2, and -3±2 degrees, respectively, while the corresponding knee flexion values were 144±4, 144±3, and 146±5 degrees respectively (Table V).

Table V. *Range of motion (ROM) measured with a goniometer 24 weeks after surgery: extension and flexion.*

	Post-op extension	Post-op flexion
NB	-3° ± 1°	144° ± 4°
AB	-2° ± 2°	144° ± 3°
RB	-3° ± 2°	146° ± 5°

The side-to-side difference in preoperative knee circumference (measured 2 cm proximally to the patella) was 1,4 ± 0.8 cm in the NB group, 1.7 ± 1.0 cm in the AB group, and 0.8 ± 0.4 cm in the RB group. Corresponding values at 6 weeks FU were 1.2±1.2 cm, 1.4±0.6 cm, and 1.5±0.5 cm in the NB, AB, and RB groups, respectively. This difference kept on decreasing with time, and at 24 weeks follow-up, the side-to-side difference was 0.3±0.2 cm in the NB group, 0.2±0.2 cm in the AB group, and 0.1±0.4 cm in the RB group, respectively (Table VI).

Table VI. *Knee circumference was measured pre-operatively and at 6- and 24-week follow-ups, and there was a side-to-side difference.*

	Pre-op	6 weeks FU	24 weeks FU
NB	1,4 ± 0.8	1.2 ± 1.2 cm	0.3 ± 0.2 cm
AB	1.7 ± 1.0	1.4 ± 0.6 cm	0.2 ± 0.2 cm
RB	0.8 ± 0.4	1.5 ± 0.5 cm	0.1 ± 0.4 cm

VAS score demonstrated a progressive decrease in all groups at 6, 12, and 24 weeks after surgery. At 24 weeks of follow-up, the average VAS score was 0.3±1.8 in the NB group, 0.7±2.1 in the AB group, and 0.6±1.4 in the RB group, respectively (Table VII).

Table VII. *Visual Analogue Scale (VAS) measured at 6-, 12-, and 24-week follow-up.*

	6 weeks FU	12 weeks FU	24 weeks FU
NB	3.2 ± 0.6	1.6 ± 0.4	0.3 ± 1.8
AB	2.8 ± 1.2	1.4 ± 0.8	0.7 ± 2.1
RB	3.4 ± 0.8	1.8 ± 0.6	0.6 ± 1.4

The Lysholm and Tegner activity scores showed a functional improvement at the 24-week evaluation: Tegner's average value was 7 in the NB, 6 in the AB group, and 6 in the RB group (Table VIII).

Table VIII. *Lysholm-Tegner score measured pre-operatively and at 24 weeks follow-up.*

	Lysholm Pre-op	Lysholm Post-op	Tegner Pre-op	Tegner Post-op
NB	66	84	7	7
AB	65	82	6	6
RB	67	82	7	6

The baseline IKDC score was 29.4 ± 2.3 in the NB group, 27.4 ± 2.1 in the AB group, and 28.2 ± 1.6 in the RB group. Corresponding values at 24 weeks, were 86.2±6, 82±12.6 and 81.6±13.2. The difference between the NB group, the AB group, and the RB group was statistically significant ($p < 0.01$) (Table IX).

Table IX. *IKDC score measured before surgery and at 24 weeks follow-up.*

	Pre-op	Post-op (24 weeks FU)
NB	29.4 ± 2.3	86.2 ± 6.0
AB	27.4 ± 2.1	82.0 ± 12.6
RB	28.2 ± 1.6	81.6 ± 13.2

DISCUSSION

The most relevant finding of the present study is the absence of any significant difference in terms of clinical scores and complications related to the use of postoperative brace (AB or RB) or not (NB). There was no significant difference between them in terms of pain, complications, functional activity (sports practice or activity daily living), muscular strength, and knee stability. Antero-posterior residual knee laxity (measured with KT-1000 arthrometer) did not show significant side-to-side difference in the three groups. Clinical satisfaction was normally distributed in the three groups. Although no difference emerged, according to Lysholm-Tegner, the IKDC score showed better results in the braceless group (statistically significant).

These data are important since rehabilitation protocols after ACL reconstruction must be safe and effective. From the literature analysis, high variability in the composition and timing of rehabilitation phases emerges. To date, no consensus exists on the most effective rehabilitation protocol (11), and there is no scientific evidence to support the routine use of a post-operative knee brace (13-15). According to the present study, there is no evidence to support the use of a brace (articulated or not) or to keep the knee immobilized or immediately mobilized. The present data are similar to those reported in other previous studies where no significant difference emerged in terms of knee joint laxity, pain, and functional activity depending on the use or not of a postoperative knee brace (24-27).

Those surgeons who support the use of knee brace affirm it ensures normalized tibiofemoral joint mechanics, increased protection on the graft and minimized stress forces (translational, rotatory, and valgus loads) across the knee. These hypotheses have been confirmed in previous biomechanical studies, which show that bracing significantly decreases pathologic anterior displacement of the tibia relative to the femur (28). Another potential effect of bracing is its influence on knee proprioception. Birmingham et al. found that knee bracing did not improve balance testing with no significant effect on balance control in challenging balance tasks (29). Risberg et al. found that knee bracing did not improve the threshold to detect passive motion after ACL reconstruction (25). These results were comparable to those of Beynnon et al. (30), who demonstrated that functional bracing or neoprene sleeve applied to an ACL-deficient knee did not improve the threshold for detection of passive knee motion. On the other side, Salehi et al. (31) showed a significant effect of functional knee bracing on postural control in double-leg stance subjects with ACL reconstruction. Palm et al. (32) showed that elastic knee braces increased postural stability in patients with ACL rupture but reported no difference in postural stability between injured and uninjured legs in the braced protocol.

On the other hand, wearing a brace can be potentially detrimental since it may result in significantly increased thigh atrophy, potential loss of knee extension, increased fatigability during rehabilitation exercises, and decreased patient perception of maximal performance (13-15). The study by Muellner et al. (26) showed that bracing after ACL reconstruction (with patellar tendon) did result in an initial reduction in knee flexion with the use of a standard rigid brace. This drawback could be avoided with the hyperextension brace (13, 33).

Several studies on functional bracing have shown that it produces significantly more thigh atrophy at 3 months than did non-bracing (25, 34). However, the thigh atrophy was reduced when the brace was removed, with no difference 6 months after surgery. In addition, these studies showed that the use of prolonged knee braces resulted in significantly decreased quadriceps muscle strength (by 12% to 30%). Lindström et al. in a prospective randomized controlled trial (RCT) on knee bracing showed that the use of post-operative bracing had no effects on the extent of joint effusion at three months and on functional outcomes at twelve months (35). Mayr et al. (15), in an RCT, compared the clinical outcomes of the rehabilitation protocol after ACL reconstruction using a hard brace and a water-filled soft brace. Patients in the soft-brace group had significantly higher IKDC subjective ratings from 6 weeks to 12 months after surgery. Using the water-filled soft brace resulted in less swelling, extension deficit, and increased patient-measured outcome, with significantly higher Tegner activity scores and Lysholm knee scores. Despite these considerations, a survey by the

American Orthopaedic Society for Sports Medicine (AOSSM) showed that post-operative bracing is used up in 85% of patients undergoing ACL reconstruction (12).

However, this clear trend is not justified by any evidence reported in the literature. The systematic review by Wright and Fetzer found no difference in the use of post-operative bracing in terms of graft stability, postoperative ROM, pain, retear rate, or protection from a new injury (14). More recently, Kruse et al. concluded that a knee brace after ACL reconstruction is neither beneficial nor necessary (36). In addition, Lobb et al. (1) showed no evidence of advantages with knee bracing (0-6 weeks postoperatively) over the no-bracing option. Finally, the review by Rodriguez-Merchan (37) on 28 articles showed that postoperative bracing after ACL reconstruction does not help reduce pain and improve knee stability and function. The authors concluded that there is no scientific evidence to support the routine use of a knee brace in the rehabilitative postoperative course following ACL reconstructions.

The present randomized controlled trial had similar results. At the final follow-up (24 weeks), there was no difference in terms of ROM, thigh atrophy, complication rate, and function that emerged from the use of a knee brace (articulated or rigid). Interestingly, no difference emerged regarding residual laxity at the last follow-up.

Although the notable findings that may influence surgeons' daily practice, the present study has some limitations. The first one is that the follow-up is quite short, and longer follow-ups may have been useful in detecting any differences in retear rate. Finally, the present study is focused only on hamstring grafts. This fact has made the study more homogeneous but may have been a bias simultaneously, excluding the potential effects of knee bracing on other grafts.

CONCLUSIONS

The present study did not show any statistical evidence to support the use of a knee brace, either fixed or articulated in the first postoperative period after ACL reconstruction. Joint stability, range of motion, pain, quadriceps circumference, functional activity, and complication rate were similar in the three groups. Therefore the presumed protective role of knee brace and prolonged extension after surgery did not result in any clinical advantage nor the rate of complications and residual laxity. Surgical technique, based on the surgeon's experience, post-operative rehabilitation program, and patient's compliance to surgeons and therapist indications seem to be more relevant to achieve satisfactory results and avoid complications. Future studies should better define the role and importance of bracing after ACL reconstruction.

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