

The Efficacy of Combined Cryotherapy and Compression Compared with Cryotherapy Alone Following Anterior Cruciate Ligament Reconstruction

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Abstract

While cryotherapy has been shown to decrease postoperative pain after anterior cruciate ligament (ACL) reconstruction, less is known of the effects of combined cryotherapy and compression. The goal of this study was to compare subjective and objective patient outcomes following ACL reconstruction with combined compression and cryotherapy compared with traditional ice therapy alone. Patients undergoing ACL reconstruction were randomized to cryotherapy/compression device (group 1) or a standardized ice pack (group 2). Both groups were instructed to use the ice or cryotherapy/compression device three times per day and return to the clinic at 1, 2, and 6 weeks postoperatively. Patient-derived outcome measurements used in this study consisted of the visual analog scale (VAS), the Lysholm knee score, Short Form-36 (SF-36), and single assessment numerical evaluation (SANE). Circumferential measurements of the knee at three locations (1 cm proximal to patella, mid-patella, and 1 cm distal to patella) were also obtained as a measure of postoperative edema. Narcotic medication use was recorded by questionnaire. The primary outcome measure (VAS) was significantly different among groups in the preoperative measurement, despite similarities in group demographics. Baseline VAS for group 1 was 54.9 compared with group 2 at 35.6 ($p = 0.01$). By 6 weeks, this had lowered to 28.1 and 40.3, respectively, resulting in a significant 27-point decrease in mean VAS for group 1 ($p < 0.0001$). However, the small increase in VAS for group 2 was not significant ($p = 0.34$). No significant differences were noted for the Lysholm, SF-36, or SANE scores either between groups or time points. Furthermore, no significant differences were noted for any of the circumferential measurements either between groups or time points. Of all patients, 83% of group 1 discontinued narcotic use by 6 weeks, compared with only 28% of group 2 ($p = 0.0008$). The use of combined cryotherapy and compression in the postoperative period after ACL reconstruction results in improved, short-term pain relief and a greater likelihood of independence from narcotic use compared with cryotherapy alone.

Keywords

- ▶ cruciate
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The utility of cold therapy for acute musculoskeletal injuries has been previously established.¹⁻⁵ Cryotherapy results in significant reductions in cellular metabolism, tissue hypoxia, edema formation, nerve conduction, and secondary pain.^{6,7} Similarly, cold treatment has been successfully used in the postsurgical treatment of orthopedic patients, particularly following anterior cruciate ligament (ACL) reconstruction,⁸⁻¹³ knee arthroscopy,¹⁴ and total knee arthroplasty.¹⁵ Although the actual therapeutic benefits have been disputed,^{4,8,14} several authors have demonstrated the efficacy of continuous cold therapy in the short-term postoperative period.^{8,9} In addition to cryotherapy, concomitant pneumatic compression may also contribute to better short-term clinical outcomes.⁷

However, few studies have adequately investigated and demonstrated the benefits of compressive cryotherapy (CC) when compared with conventional ice treatment alone. The purpose of this study was to evaluate and compare the effectiveness of cryotherapy with or without intermittent pneumatic compression after arthroscopic ACL reconstruction, with a focus on postoperative edema, pain, and patient-reported outcome measures. We hypothesized that CC would produce improved subjective patient outcomes and decreased postoperative edema when compared with conventional ice therapy.

Methods

In this prospective, randomized controlled trial was approved by our institutional review board. All consecutive patients presenting to a single institution for ACL reconstruction were approached for involvement in this study. Exclusion criteria were patient age less than 18 or over 65, morbid obesity greater than or equal 40 kg/m², comorbid fracture or multi-ligamentous knee injury, partial ACL injury, history or significant risk factors for deep venous thrombosis or pulmonary embolus, significant arteriosclerosis or ischemic peripheral vascular disease in the operative extremity, chronic venous or lymphatic insufficiency in the operative extremity, history of narcotic use greater than 3 months before surgery, or concurrent diagnosis of fibromyalgia or chronic regional pain disorder involving the operative extremity.

At the preoperative visit, patients were enrolled and consented for involvement in this study. Subjects were randomized to one of two postoperative treatment groups utilizing a random number generator with even identification numbers assigned to the CC group (Game Ready[®], CoolSystems, Inc., Alameda, CA) and odd identification numbers assigned to the control (C) group (conventional ice pack therapy). Instructions were provided regarding application and use of each type therapy for at least three sessions per day for 30 minutes duration. Treatment compliance was documented for comparison.

The same standard postoperative ACL rehabilitation protocol was used for both groups. Active assist range of motion from 0 to 90° with passive extension was allowed during the first 2 weeks with braced weight bearing as tolerated in extension. At 2 weeks, closed chain exercises and full, active

range of motion were initiated, and brace wear was discontinued at 4 weeks. Light running was resumed at 3 to 4 months, with full running at 4 to 6 months and contact sports permissible after 6 months. Protocol modifications were implemented for meniscal repair or other concomitant procedures.

Postoperative follow-up appointments were scheduled at 1, 2, and 6 weeks postoperatively for routine care and questionnaire completion including the visual analog scale (VAS), Short Form-36 (SF-36), single assessment numerical evaluation (SANE), Lysholm scores, and medication usage. Three circumferential measurements (cm) were obtained of the operative extremity taken at mid-patella, and 1 cm proximal and distal to the respective margins of the patella with the knee in full extension. All postoperative appointments were scheduled for 8:00 AM to avoid secondary edema from physical therapy, prolonged daily use of the extremity, and continuous upright activity. Postoperative outcome measures were compared with baseline values obtained at preoperative enrollment.

Statistical Analysis

Our power analysis was performed to recognize a VAS change of 10 mm out of 100 mm and recommended 16 patients per group. Parametric outcome measures were compared using the general linear mixed model analyses for repeated measures and the Student *t*-test to assess for statistical significance, with significance set at $p < 0.05$. Fisher's exact test and chi-square test were employed for comparing compliance rates and discontinued use of all pain medications rates at 6 weeks. Kaplan-Meier survival analysis with the log-rank test was employed for comparing the curves of the rates of discontinuation of narcotic pain medication over time between the two groups.

Results

Patients from groups 1 and 2 were compared for sampling differences by percentage of male or female sex, mean age, mean weight, mean tourniquet time, and frequency of associated surgery. No statistically significant differences ($p > 0.05$) were noted across any parameters (→ **Table 1**).

Compliance

Patients underwent appropriate training on therapy application and use. Subsequent assessments of compliance were performed at 1, 2, and 6 weeks postoperatively. During weeks 1 and 2, patients with CC had 100% ($n = 18$) compliance with use compared with 83% ($n = 18$) of the C group ($p = 0.23$). By week 6, compliance in both CC (28%; $n = 5$) and C (39%, $n = 7$) were both decreased and demonstrate no significant differences ($p = 0.73$).

Narcotic Medication Use

At 6 weeks postoperatively, 15 of 18 (83.3%) of all patients in the CC group had discontinued use of all pain medication, compared with 5 of 18 patients (27.8%) in the C group ($p = 0.0008$). Similarly, survivorship analysis with continuing

Table 1 Demographic and Surgery Parameters of Control and Compressive Cryotherapy Groups

	Control	Compressive Cryotherapy
Male/female (N)	15/3	15/3
Age (years)	30.9	28.7
Weight (lbs)	179.2	188.1
Height (in)	68.5	69.0
Tourniquet time (minute)	98.6	102.4
Concomitant surgery (N)	11	13
Graft type (allograft/autograft)	10/8	8/10

Note: No statistically significant differences were detected between control and compressive cryotherapy groups in all categories.

use of narcotic medication as an end point demonstrated statistically significant difference between groups ($p = 0.0023$; ► Fig. 1).

Knee Circumference

Circumferential measurements of the knee demonstrated no statistically significant differences between or within the two groups across any time intervals. Both groups showed increased measurements at the first postoperative week and a consistent trend toward baseline measurements at the second and sixth postoperative weeks (► Table 2).

VAS

The preoperative VAS values were significantly different between groups. The VAS values for postoperative week 1 were significantly increased from baseline in both groups. Comparison of absolute VAS values between groups at all postoperative points revealed no statistically significant differences. However, when evaluating for mean differences in VAS relative to the preoperative measurement, the CC group had significantly better improvements in VAS than the C group at postoperative week 2 ($\Delta\text{VAS}^{\text{CC}} = -4.11$; $\Delta\text{VAS}^{\text{C}} = +15.67$; $p = 0.023$) and week 6 ($\Delta\text{VAS}^{\text{CC}} = -26.83$; $\Delta\text{VAS} = +4.72$; $p < 0.0001$). Comprehensive results for VAS are indicated in ► Table 3.

Subjective Patient Outcome Scores

There were no statistically significant differences detected in any of our measured subjective scoring systems. In the SF-36

scores, no statistically significant differences ($p > 0.05$) were detected between the C and the CC groups at all time intervals (► Table 4). Average SANE scores were higher in the cooling compression group at 1, 2, and 6 weeks postoperatively when compared with the C group, although none of these differences achieved statistical significance ($p > 0.05$, ► Table 5). When evaluated by Lysholm scores, no statistically significant differences ($p > 0.05$) were detected between C and CC at all time intervals (► Table 6).

Wound Complications

No cold-related wound complications, including frostbite or transient nerve palsy, occurred in patients in either C or CC groups.

Discussion

Cold therapy, also known as cryotherapy, has been frequently used for musculoskeletal trauma and the postoperative treatment of orthopedic patients. Several in-vivo studies have demonstrated the efficacy of conventional ice therapy and commercial cryotherapy systems in reducing skin, intramuscular, and intra-articular temperature in healthy volunteers,¹⁶ patients with inflammatory conditions,^{17,18} and those after surgery,¹⁹ including ACL reconstruction.^{6,10,13,20} While the optimal duration and frequency of cryotherapy are often subject to debate,²¹ many authors assert that lower temperatures contribute to decreased tissue metabolism, localized vasoconstriction, diminished inflammatory mediator release, hypoxia, and attenuated nerve conduction with a resultant decrease in secondary edema, pain, and spasm.^{6,22}

Several clinical studies have demonstrated improvement in objective and subjective outcome measures with cryotherapy after ACL reconstruction. Cohn et al⁹ showed over 50% less injectable narcotic and sedative use in patients, quicker transition to oral pain medication, and greater mobility and performance in physical therapy with patients using cryotherapy when compared with controls. More recently, Barber et al⁸ also showed lower VAS and Likert scores, reduced oral narcotic use, greater knee flexion, and improved overall range of motion with continuous-flow cold therapy than noncold controls. In their meta-analysis, Raynor et al²² also confirmed that patients receiving cryotherapy had significantly lower

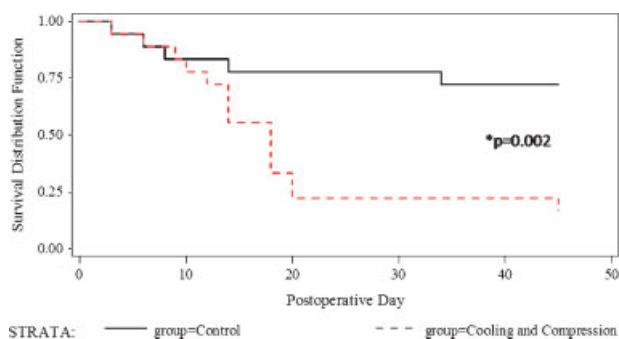


Figure 1 Survivorship analysis of patients with discontinuation of narcotic pain medication as end point.

Table 2 Circumferential Knee Measurements with Compressive Cryotherapy or Control Groups after Anterior Cruciate Ligament Reconstruction

	Proximal Patella		Central Patella		Distal Patella	
	Compressive Cryotherapy	Control	Compressive Cryotherapy	Control	Compressive Cryotherapy	Control
Preoperative	40.74	41.22	39.19	39.69	36.14	37.50
1 week	44.14	44.00	41.39	41.89	38.08	39.31
2 weeks	42.94	41.83	40.31	40.08	37.42	37.92
6 weeks	41.36	41.28	39.67	39.97	36.83	37.61

Note: All circumferential knee measurements are expressed in centimeters. No significant differences were found between groups or time periods.

Table 3 VAS with Control and Compressive Cryotherapy after Anterior Cruciate Ligament Reconstruction

VAS	Control (95% CI ^a)	Mean Difference (Δ VAS ^C) ^b	Compressive Cryotherapy (95% CI ^a)	Mean Difference (Δ VAS ^{CC}) ^b	<i>p</i> Value
Baseline	35.61 (22.25, 48.97)	–	54.89 (45.01, 64.77)	–	–
1 week	57.78 (44.13, 71.42)	+22.17	65.50 (56.33, 74.67)	+10.61	0.072
2 weeks	51.28 (38.14, 64.42)	+15.67	50.78 (43.24, 58.31)	–4.11	0.002
6 weeks	40.33 (28.95, 51.17)	+4.72	28.06 (19.92, 36.19)	–26.83	<0.001

^a95% CI represents 95 percent confidence intervals.

^b Δ VAS^C and Δ VAS^{CC} represent changes in VAS at 1, 2, and 6 weeks postoperatively relative to baseline measurements in both control and compressive cryotherapy groups, respectively.

VAS, visual analog scale.

Table 4 SF-36 Scores in Control and Compressive Cryotherapy after Anterior Cruciate Ligament Reconstruction

SF-36	Control (95% CI ^a)	Mean Difference (Δ SF-36 ^C) ^b	Compressive Cryotherapy (95% CI ^a)	Mean Difference (Δ SF-36 ^{CC}) ^b	<i>p</i> Value
Baseline	32.53 (26.40, 38.66)	–	27.87 (21.15, 34.59)	–	–
1 week	26.13 (20.41, 31.84)	–6.40	27.45 (20.24, 34.66)	–0.42	0.149
2 weeks	21.06 (14.28, 27.84)	–11.47	20.85 (12.28, 29.41)	–7.02	0.384
6 weeks	16.41 (10.40, 22.42)	–16.11	18.12 (8.73, 27.50)	–9.75	0.306

^a95% CI represents 95 percent confidence intervals.

^b Δ SF-36^C and Δ SF-36^{CC} represent changes in Short Form-36 scores at 1, 2, and 6 weeks postoperatively relative to baseline measurements in both control and compressive cryotherapy groups, respectively.

Table 5 SANE Score in Control and Compressive Cryotherapy after Anterior Cruciate Ligament Reconstruction

SANE	Control (95% CI ^a)	Mean Difference (Δ SANE ^C) ^b	Compressive Cryotherapy (95% CI ^a)	Mean Difference (Δ SANE ^{CC}) ^b	<i>p</i> Value
Baseline	67.22 (51.15, 83.30)	–	70.11 (54.60, 85.62)	–	–
1 week	65.00 (48.35, 81.65)	–2.22	68.61 (55.00, 82.22)	–1.50	0.862
2 weeks	69.17 (53.81, 84.52)	+1.94	75.56 (62.32, 88.79)	+5.44	0.241
6 weeks	70.83 (55.52, 86.14)	+3.61	73.89 (58.08, 89.70)	+3.78	0.984

^a95% CI represents 95 percent confidence intervals.

^b Δ SANE^C and Δ SANE^{CC} represent changes in single assessment numerical evaluation scores at 1, 2, and 6 weeks postoperatively relative to baseline measurements in both control and compressive cryotherapy groups, respectively.

Table 6 Lysholm Score in Control and Compressive Cryotherapy after Anterior Cruciate Ligament Reconstruction

Lysholm	Control (95% CI) ^a	Mean Difference (Δ Lysholm ^C) ^b	Compressive Cryotherapy (95% CI) ^a	Mean Difference (Δ Lysholm ^{CC}) ^b	<i>p</i> Value
Baseline	65.0 (56.01, 73.99)	–	54.0 (44.62, 63.38)	–	–
1 week	57.72 (49.46, 65.99)	–7.28	47.83 (39.28, 56.39)	–6.17	0.881
2 weeks	58.72 (49.12, 68.33)	–6.28	56.94 (48.83, 65.06)	+2.94	0.218
6 weeks	68.67 (60.24, 77.10)	+3.67	66.89 (58.46, 75.32)	+12.89	0.212

^a95% CI represents 95 percent confidence intervals.

^b Δ Lysholm^C and Δ Lysholm^{CC} represent changes in Lysholm scores at 1, 2, and 6 weeks postoperatively relative to baseline measurements in both control and compressive cryotherapy groups, respectively.

postoperative pain, although there were no significant differences with regards to postoperative drainage or range of motion.

However, despite its ubiquitous use, several authors have disputed the beneficial effects of cryotherapy^{13,23} and identified its rare, implicit risks.^{24–26} In patient groups with five different temperature (room temperature, 40, 45, 55, and 70 F) settings after ACL reconstruction, Daniel et al²³ showed no differences in hospital stay, pain medication use, self-reported pain level, knee circumference, or overall range of motion between groups. Konrath et al¹³ similarly demonstrated no difference in hospital stay, pain medication use, drain output, or overall range of motion in a comparison of patients with or without cryotherapy. Furthermore, transient nerve palsies^{9,24} and frostbite^{25,26} from postoperative cryotherapy have been reported, although no complications were encountered in the current study.

The merits of concomitant compression with cryotherapy have also been debated in the literature. The addition of compression appears to contribute additional benefits with traumatic soft tissue injuries¹ and in the postsurgical patient^{5,15,27} and it results in local reductions in blood flow and edema that are superior to extremity elevation alone.²⁸ In their study of patients undergoing ACL reconstruction, Schröder and Pässler⁷ substantiated these claims by showing lower self-reported pain scores, analgesic consumption, postoperative swelling along with improved range of motion, and functional knee scores with CC when compared with ice use alone. Barber²⁷ also described lower VAS and Likert scores, lower narcotic use, and improved compliance with CC versus crushed ice alone. Conversely, Dervin et al²⁹ and Edwards et al¹¹ showed no significant differences in VAS, analgesic use, range of motion, or postoperative drainage.

In this prospective, randomized controlled trial, we demonstrate that CC provides superior short-term, patient-reported outcomes, improved pain relief, and earlier discontinuation of narcotic medication use after ACL reconstruction when compared with the ice therapy alone. However, no significant differences were detected in patient compliance with treatment, postoperative edema as measured by limb circumference, or other subjective patient outcome scores including the SF-36, SANE, and Lysholm score. This study offers numerous advantages, largely as a result of its rigorous design as a prospective, randomized controlled trial. The young, active

military population used in this study was fairly homogenous with minimal additional medical comorbidities and centralized physical therapy. Multiple primary and secondary outcome measures, including both objective and subjective parameters, were obtained for comparative analysis.

However, certain limitations must also be acknowledged. Patients from multiple operating providers were included in this study. Due to the nature of the study, patient blinding was also not possible, thus introducing potential responder and treatment bias. The difference in preoperative VAS score between groups was not anticipated and represents a potential source of bias. The groups did not appear to be different in other measured parameters. We elected to compare the change in VAS to account for this preoperative difference. No differences were evident in the SF-36, SANE, or Lysholm scores. However, these secondary patient outcome measures are not validated measures of postoperative pain, but are included for completeness. We also cannot explain the absence of difference in circumferential measurements, as this removal of postoperative swelling was anticipated as the mechanism for pain relief in the cooling and compression group.

We assert that cryotherapy and intermittent compression contribute additional short-term benefits. In the current study, patients undergoing ACL reconstruction with postoperative CC had improved pain relief and earlier discontinuation of narcotic pain medication. The use of CC systems may improve short-term outcomes through reduction of narcotic pain medication use and enhancement of perioperative pain control. Further research should evaluate the comparative differences in commercially available systems, as well as other potential applications outside the knee.

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