



■ TECHNIQUES IN KNEE RECONSTRUCTION

A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery

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Pain, swelling and inflammation are expected during the recovery from total knee arthroplasty (TKA) surgery. The severity of these factors and how a patient copes with them may determine the ultimate outcome of a TKA. Cryotherapy and compression are frequently used modalities to mitigate these commonly experienced sequelae. However, their effect on range of motion, functional testing, and narcotic consumption has not been well-studied.

A prospective, multi-center, randomised trial was conducted to evaluate the effect of a cryopneumatic device on post-operative TKA recovery. Patients were randomised to treatment with a cryopneumatic device or ice with static compression. A total of 280 patients were enrolled at 11 international sites. Both treatments were initiated within three hours post-operation and used at least four times per day for two weeks. The cryopneumatic device was titrated for cooling and pressure by the patient to their comfort level.

Patients were evaluated by physical therapists blinded to the treatment arm. Range of motion (ROM), knee girth, six minute walk test (6MWT) and timed up and go test (TUG) were measured pre-operatively, two- and six-weeks post-operatively. A visual analog pain score and narcotic consumption was also measured post-operatively.

At two weeks post-operatively, both the treatment and control groups had diminished ROM and function compared to pre-operatively. Both groups had increased knee girth compared to pre-operatively. There was no significant difference in ROM, 6MWT, TUG, or knee girth between the 2 groups. We did find a significantly lower amount of narcotic consumption (509 mg morphine equivalents) in the treatment group compared with the control group (680 mg morphine equivalents) at up to two weeks postop, when the cryopneumatic device was being used ($p < 0.05$). Between two and six weeks, there was no difference in the total amount of narcotics consumed between the two groups. At six weeks, there was a trend toward a greater distance walked in the 6MWT in the treatment group (29.4 meters *versus* 7.9 meters, $p = 0.13$). There was a significant difference in the satisfaction scores of patients with their cooling regimen, with greater satisfaction in the treatment group ($p < 0.0001$). There was no difference in ROM, TUG, VAS, or knee girth at six weeks. There was no difference in adverse events or compliance between the two groups.

A cryopneumatic device used after TKA appeared to decrease the need for narcotic medication from hospital discharge to 2 weeks post-operatively. There was also a trend toward a greater distance walked in the 6MWT. Patient satisfaction with the cryopneumatic cooling regimen was significantly higher than with the control treatment.

Recovery from surgery is characterised by pain, swelling, and inflammation in the peri-operative tissues. This is especially true after total knee arthroplasty (TKA) surgery, because of the high concentration of nerve endings around the knee, the amount of bone resection, and bleeding in an enclosed space (joint capsule). These factors may make it difficult for patients to comply with the prescribed post-operative physical therapy regimen of mobilisation and regaining range of motion of the knee. Consequently, the patient's ability to

cope with post-operative pain, swelling, and inflammation may influence function of the newly implanted knee and his/her ultimate result.

Compression and cryotherapy have been traditionally used in the post-operative recovery of TKA to mitigate these factors. Compression is thought to decrease oedema by increasing hydrostatic pressure, thereby reducing the outflow of fluid into the interstitial space. In the closed environment of the knee capsule, compression may also reduce the intra-articular volume, limiting the amount of

hemarthrosis that can accumulate. Cryotherapy can reduce leukocyte migration and slow down nerve signal transmission, providing a reduction of inflammation and producing a short-term analgesic effect. Using a device that provided cryotherapy and static compression to a knee after arthroscopic surgery, researchers found a significantly lower concentration of prostaglandin E₂, a cytokine commonly associated with inflammation, confirming this theorised benefit.¹ In combination, compression and cryotherapy can potentially reduce pain, oedema, inflammation and swelling, thereby enhancing recovery.

Orthopedic studies examining the benefits of cryotherapy and compression on recovery after TKA have shown a reduction in blood loss by diminishing suction output from a drain.²⁻⁴ However, the clinical benefits on pain and range of motion have been equivocal, with some studies showing a benefit,³⁻⁶ and others showing no difference in the treatment group.^{2,7-9} The same is true of studies examining the effect on knee arthroscopy patients, with some demonstrating benefit^{10,11} and others showing no difference.¹² Besides the limitations of small numbers of subjects, or being non-randomised, unblinded, cohort studies, the treatment was only applied while the patients were in hospital (typically less than one week).

We believe that compression and cryotherapy can have a beneficial role in post-TKA recovery; thus we sought to investigate their effect with a randomised, multi-center, blinded trial comparing the use of a new compression and cryotherapy device to a regimen of ice and static compression. We wanted to enroll a larger number of patients, with a defined treatment protocol for each group. Furthermore, we lengthened the treatment to two weeks post-operative to evaluate the effect of extended treatment. Blinded observations were scheduled at multiple timepoints post-operatively to assess progress.

Our goals for the study were to evaluate whether there would be differences in pain, swelling, range of motion, functional testing, and consumption of pain medication between a group of patients undergoing cryotherapy and intermittent pneumatic compression vs. ice and static compression after TKA surgery.

Patients and methods

Patients were eligible for inclusion if they were between the ages of 18 and 85 with a diagnosis of unilateral osteoarthritis. Eleven sites were selected for participation in the study; each institutional review board gave permission for the study. The eleven sites were as follows: Hospital for Special Surgery (New York); San Antonio Military Medical Center (Fort Sam Houston, Texas), Cleveland Clinic (Cleveland, Ohio), Indiana Orthopedic Hospital (Indianapolis, Indiana), Tripler Army Medical Center (Honolulu, Hawaii); Madigan Army Medical Center (Tacoma, Washington), Sports Medicine Associates of San Antonio (San Antonio, Texas), Midwest Orthopedics at Rush Presbyterian (Chicago, Illinois); Olympic Park Hip and Knee Clinic



Fig. 1

The GameReady™ device (CoolSystems, Inc) is a self-contained unit that has a reservoir that can be filled with ice and water. The circumferential wrap used in the treatment group can be placed around the thigh, knee, and calf

(Sydney, Australia), Eastern Maine Medical Center (Bangor, Maine), and San Diego Naval Medical Center (San Diego, California). A maximum of 75 patients were allowed at any one site. Randomisation was carried out using a random number generator and only known by the operating surgeon and patient.

Patients were evaluated pre- and post-operatively by a physical therapist experienced in the conduction of functional assessments and blinded to the treatment arm. Knee range of motion was measured with the use of a hand-held goniometer, and girth was measured at three different locations: superior, middle, and inferior to the patella. A six minute walk test (6MWT) and a timed up and go (TUG) test were given, as was a visual analog scale (VAS) of pain. The 6MWT was conducted by measuring the distance a patient could walk, with or without assistive devices, on a level surface, in 6 minutes. The TUG test was conducted by timing how long it took for patients to rise, unassisted, from a standard, seated position. Patients were evaluated pre-operatively, at two weeks, and six weeks post-operative. A satisfaction survey from 1 (= not at all satisfied) to 6 (completely satisfied) was administered to each patient at the conclusion of the study.

Post-operatively, patients were treated with either the GameReady™ cryopneumatic device (CoolSystems, Inc; San Diego, CA) (Fig. 1), or ice and a static compression bandage. Both treatment regimens were initiated within three hours of surgery and applied for two hours on, and one hour off for a minimum of four cycles per day. After discharge from the hospital, the application time was one hour on, and 30 minutes off.

The cryopneumatic device was applied with the use of a circumferential wrap over the entire thigh and calf. The amount of cooling was titrated by each patient to their tolerance; the amount of compression was initially set at low (15 mm of Hg), but patients could adjust this once they were discharged to medium (50 mm Hg) or high (75 mm

Table I. Comparison of assessments at two weeks post-operatively. Negative values indicate a decrease from preoperative values

	Test group			p-value	Control group		
	Mean	Min	Max		Mean	Min	Max
Six minute walk test (meters)	-118.2	-387.2	131	Not significant	-107.7	-495.0	226
Timed up and go test (seconds)	4.5	-22.9	50.3	Not significant	5	-63.9	85.4
Visual analogue scale	-9.0	-77.4	53.8	Not significant	-13.5	-73.8	65.2
Flexion (°)	-33.0	-81.5	9.5	Not significant	-28.7	-75.5	19.5
Extension (°)	1.5	-29.0	18.0	Not significant	1.6	-17.0	15.5

Table II. Comparison of assessments at six weeks post-operatively. Negative values indicate a decrease from pre-operative values

	Test group			p-value	Control group		
	Mean	Min	Max		Mean	Min	Max
Six minute walk test (meters)	29.4	-179.0	335.7	0.13	7.9	-263.0	40.3
Timed up and go test(seconds)	-1.5	-20.7	6.1	Not significant	-2.4	-71.2	7.0
VAS	-23.4	-82.8	47.9	Not significant	-22.1	-77.5	85.0
Flexion (°)	-9.5	-61.5	26	Not significant	-8.6	-67.5	49.0
Extension (°)	-1.7	-30.0	17.0	Not significant	-1.5	-20.5	12.5

Hg). The intermittent regime of pneumatic compression consisted of cycling compression at the set level for 15 minutes, followed by no compression.

The number of patients who achieved four milestones was also recorded at each post-operative timepoint: 1) active flexion to 110°; 2) active extension to 0°; 3) a normal, unassisted gait pattern; 4) unassisted sit to stand. Statistical analysis was performed using SPSS version 12 (SPSS Inc, Chicago, Illinois).

Results

294 patients were enrolled in the study, but only 187 patients had complete data of knee ROM, girth, functional testing, and VAS at all timepoints (pre-operative, two- and six-weeks). A total of 103 patients received the cryopneumatic treatment and 84 patients used ice and static compression. Both groups were comparable with respect to gender, ethnicity, age and body mass index.

At two weeks, there was no significant difference between the study and control groups with respect to knee girth or ROM. Both groups had decreased ROM and increased knee girth compared with pre-operative values. Furthermore, at two weeks post-operative, both cohorts were significantly less functional and had higher VAS scores than their pre-operative assessments; there was no statistically significant difference between the groups (Table I)

With regard to consumption of pain medication during the first 2 weeks, we found a statistically significantly lower amount of morphine equivalents used by the cryopneumatic group (mean 509 mg, (15 mg to 1460 mg)) as compared with the ice and static compression group (mean 680 mg, 20 mg to 3225 mg) ($p < 0.05$). After discontinuation of the cooling and compression regimen, we did not find a

difference in narcotic consumption between the two groups between two to six weeks.

At six weeks followup, both groups had similar girth, VAS, and ROM (Table II). The cryopneumatic group walked an average of 29.4 meters as compared with 7.9 meters for the control group, but this did not reach statistical significance ($p = 0.13$). Similar percentages of patients in each group reached the functional milestones of being able to sit to stand; achieving full extension and greater than 110° of flexion, and being able to walk without a limp (Table III).

Patient satisfaction was significantly higher in the cryopneumatic device group (Table IV), with patients expressing a better rate of pain control and relief of stiffness with the device versus ice.

Compliance rates were similar between the two groups. There were no significant differences in the incidence of adverse events between the two groups. One patient in each group had blistering around the incision; six patients in the test group had manipulation under anesthesia and seven patients (8.3%) in the control group underwent manipulation. Eleven patients in the test group and eight patients in the control group had blood transfusions.

Discussion

Patients who were treated with a cryopneumatic device after TKA consumed significantly less narcotics than patients who used ice and static compression. The mean difference in pain medication consumption was 171 mg of morphine, or approximately 14 mg less per day. Although we did not find a statistically significant difference in ROM, swelling, or functional testing between the two groups, the diminished narcotic consumption may translate

Table III. Comparison of percentage of patients achieving functional milestones at six weeks post-operatively

Endpoint	Test group		p-value	Control group	
	Total	% yes		Total	% yes
Sit to stand	82/103	80%	Not significant	66/84	79%
0° extension	52/103	50%	Not significant	52/84	62%
110° flex	59/103	57%	0.3	41/84	49%
Ambulate without limp	64/103	62%	Not significant	48/84	57%

Table IV. Comparison of mean satisfaction scores between the two groups. A score of 1 = least satisfied; 6 = most satisfied

Satisfaction Question	Test group	Control group	P-value
How well did it relieve pain from surgery?	5.18	4.45	< 0.0001
How well did it relieve pain from physical therapy?	5.19	4.7	< 0.002
How well did it relieve stiffness?	4.68	4.26	< 0.02
How do you rate comfort of use?	5.44	4.64	< 0.0001
How likely would you be to use it again?	5.65	4.47	< 0.0001

to a clinical benefit of fewer side effects, such as constipation, nausea, light-headedness. As a result, patients may experience a more pleasant recovery and feel less medicated.

Patients were significantly more satisfied with the cryopneumatic device regimen as compared to ice and static compression. Patients felt that it relieved pain better after surgery and PT, was more comfortable, and they had a greater desire to use it again. These improved satisfaction scores likely arise from the fact that the device was convenient, since one filling of the reservoir can last for several treatments. Furthermore, the circumferential wrap is easy to apply. These higher satisfaction scores will likely result in higher compliance.

The limitations of our study include the fact that it was performed at 11 different sites, which may result in some variability in measurements of functional tests, girth, and ROM. However, each site had a training session by the study sponsor to ensure standardisation of testing. Furthermore, the surgical procedures were carried out by different surgeons, using the implants of their choice, which may also lead to variability in results. However, we believe that conducting the study at multiple sites allows it to be more generalisable.

Although our original hypothesis of cryopneumatic treatment leading to greater gains in ROM was not supported by our study, we were pleased that pain medication consumption was reduced. There was a trend ($p = 0.13$) toward a greater distance walked in the 6MWT, administered at six weeks post-operatively. The greater satisfaction with the cooling regimen may also enhance compliance. Therefore we find that use of a cryopneumatic compression device is beneficial during TKA recovery.

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