

2011

Is continuous flow cold compression therapy better than ice and/or compression alone for the treatment of post-operative Total Knee Replacements?

Shane Rushing
Pacific University

Follow this and additional works at: <http://commons.pacificu.edu/ptcats>



Part of the [Physical Therapy Commons](#)

Notice to Readers

This work is not a peer-reviewed publication. Though the author of this work has provided a summary of the best available evidence at the time of writing, readers are encouraged to use this CAT as a starting point for further reading and investigation, rather than as a definitive answer to the clinical question posed or as a substitute for clinical decision-making.

Select copyrighted material from published articles may be included in this CAT for the purpose of providing a context for an informed critical appraisal. Readers are strongly encouraged to seek out the published articles included here for additional information and to further examine the findings in their original presentation. Copyrighted materials from articles included in this CAT should not be re-used without the copyright holder's permission.

Recommended Citation

Rushing, Shane, "Is continuous flow cold compression therapy better than ice and/or compression alone for the treatment of post-operative Total Knee Replacements?" (2011). *PT Critically Appraised Topics*. Paper 26.
<http://commons.pacificu.edu/ptcats/26>

This Critically Appraised Topic is brought to you for free and open access by the School of Physical Therapy at CommonKnowledge. It has been accepted for inclusion in PT Critically Appraised Topics by an authorized administrator of CommonKnowledge. For more information, please contact CommonKnowledge@pacificu.edu.

Is continuous flow cold compression therapy better than ice and/or compression alone for the treatment of post-operative Total Knee Replacements?

Disciplines

Physical Therapy

Rights

Terms of use for work posted in CommonKnowledge.

CRITICALLY APPRAISED TOPIC

Title: Is continuous flow cold compression therapy better than ice and/or compression alone for the treatment of post-operative Total Knee Replacements?

Clinical Scenario:

The patient who led me to pursue this question is: A 62 y/o female s/p Total Knee Replacement (TKA) with moderate knee edema, range of motion (ROM) deficits, and gait abnormalities. Medical treatment to date has included medication, ice, rest (non-use), elevation, compression bandages, and continuous flow cold compression therapy.

Brief introduction:

For the purposes of my clinical question, I want to know what the research says about the effect of continuous flow cold compression therapy on patients in outpatient physical therapy following a TKA surgery. These patients often have edema, ROM deficits, decreased lower extremity (LE) strength/balance, and associated gait abnormalities. The clinic in which I am currently interning uses an expensive and high tech Game Ready machine for edema reduction, an alternative to crushed ice, ice pack, compression bandaging, and a similar but cheaper 'cold cuff' device.

My Clinical question: Is continuous flow cold compression therapy better than ice and/or compression alone for the treatment of post-operative Total Knee Replacements?

Clinical Question PICO:

Population – Patients in outpatient physical therapy following a total knee replacement surgery.

Intervention – Game Ready (continuous flow cold compression therapy)

Comparison – Medication, Rest (non-use), crushed ice, compression bandaging, cold cuff device

Outcome – Pain (visual analog scale), ROM (PROM/AROM), Edema (circumferential measurement), medication use

Overall Clinical Bottom Line: Based on the results of the outcomes from Healy *et al.* and Barber *et al.*...

Due to the poor/fair study designs of both articles and the difference in interventions and patient populations between them, I can state that these studies gave me only a few pieces to answer my clinical question. First of all, I can say with moderate confidence that the continuous flow cold therapy machine is more effective than crushed ice in increasing knee PROM and decreasing pain (but not vicodin use) in the first week following ACL repair surgery. It is also important to note that the machine is very expensive compared the small amount of insurance reimbursement per PT billing code.

Secondly, the costs of the Cryo Cuff (an older version of the Game Ready without continuous flow) outweigh its possible benefits (ROM, swelling, narcotic use) when substituted for ice and compression bandaging in patients following TKA surgery. Together these studies would not convince me to buy a Game Ready machine for my outpatient clinic. However, if my clinic already had one I would use it with both TKA and ACL repair patients.

Search Terms: Game Ready, cryotherapy, continuous flow, cold compression

Appraised By: Shane Rushing, SPT
School of Physical Therapy
College of Health Professions
Pacific University
Hillsboro, OR 97123
rush1724@pacificu.edu

Rationale chosen articles:

It was a difficult process to pick the two best articles out of these three. There were two variables that made this decision difficult. First of all, I wanted these articles to use the Game Ready machine as their intervention. Unfortunately, this product was created about ten years ago and all of the TKA related research is from over 10 years ago when the Cryo Cuff was used. Secondly, I wanted to compare the Game Ready to the less expensive use of crushed ice with an ace wrap. Again, the only article with this comparison also used a Cryo Cuff.

In the end, I chose the Healy article because it compared the “cryo cuff” to ice and ace wrap with TKA’s. Even though they didn’t use the Game Ready. Also, I chose the Barber article because they compared a Game Ready (or at least a similar device) to ice alone following ACL repair surgery. Finally, I eliminated the Webb article that compared the Cryo Cuff to normal bandaging alone in TKA’s. Its results suggested that the Cryo Cuff is more effective than bandaging. I eliminated this one because it’s unrealistic to think that a patient won’t get some kind of cryotherapy following a TKA.

Articles:

Healy WL, Seidman J, Pfeifer BA, Brown DG. Cold compressive dressing after total knee arthroplasty. *Clinical Orthopaedics and Related Research* 1994 Feb;(299):143-146

PEDro Score 2/10

Patient: 105 knees of 76 patients following TKA surgery

Intervention: Cryo Cuff

Comparison: Ice and ace wrap

Outcome measures: ROM, Swelling, Narcotic use, wound drainage

Webb JM, Williams D, Ivory JP, Day S, Williamson DM. The use of cold compression dressings after total knee replacement: a randomized controlled trial. *Orthopedics* 1998 Jan;21(1):59-61.

PEDro Score 5/10

Patient: 40 patients s/p TKA surgery

Intervention: Cryo Cuff

Comparison: Wool and Crepe dressing

Outcome measures: blood loss, pain, swelling, ROM

Barber FA. A comparison of crushed ice and continuous flow cold therapy.

American Journal of Knee Surgery. 2000 Spring;13(2):97-101.

PEDro Score ?/10

Patient: 87 patients s/p ACL repair surgery

Intervention: Mechanical continuous flow therapy

Comparison: Crushed Ice

Outcome measures: Pain, ROM, narcotic use

Table 1. Comparison of PEDro Scores

	Healy <i>et al.</i>	Webb <i>et al.</i>	Barber <i>et al.</i>
Random	YES	YES	?
Concealed allocation	NO	YES	?
Baseline comparability	NO	NO	?
Blind Subjects	NO	NO	?
Blind Therapists	NO	NO	?
Blind Assessors	NO	YES	?
Adequate Follow-up	NO	NO	?
Intention-to-Treat	NO	NO	?
Between Group	YES	YES	?
Point Estimates & Variability	NO	YES	?
Total Score	2/10	5/10	?/10 (not assessed)

Based on the above comparisons, I have chosen to write this critically appraised paper on the articles by Healy *et al.* and Barber.

Article: Healy *et al.*, 1994.

Clinical Bottom Line: This study did not answer my clinical question. There were significant threats to internal and external validity, including an overall poor study design and some dissimilarities to my clinical intervention and population. Despite this, the study suggests that the costs of the Cryo Cuff outweigh its possible benefits (ROM, swelling, narcotic use) when substituted for ice and compression bandaging in patients following TKA surgery.

Article PICO:

Patient: 105 knees of 76 patients following TKA surgery

Intervention: Cryo Cuff

Comparison: Ice and ace wrap

Outcome measures: ROM, Swelling, Narcotic use, wound drainage

Blinding: The subjects, therapists, and assessors were not blinded in this study. Only the assessors could have been blinded in this type of study. Still, this most likely poses a threat to internal validity.

Controls: The control group received crushed ice in a sack with an ace wrap around it. It was unclear if the frequency of the intervention being applied for the control group matched the frequency for the treatment group. I believe that this was an appropriate intervention for the control group because it is a historically standard and cheap way of applying cold and compression.

Randomization: The subjects were randomized into the groups. The randomization of subjects was not stratified or concealed. The subjects weren't measured at baseline, so there was no way of knowing if the randomization was successful or not.

Study: The design of this study was a randomized controlled trial. It was, however, a poorly designed one (blinding, baseline measurements, etc). There were two treatment groups and two control groups. There were a control and treatment group that were studied in "Phase 1" and a control and treatment group studied in "Phase 2". My understanding is that they performed the study at two different times, with different patients, using different intervention frequencies. In Phase 1 the Cryo Cuff ice water was changed every 4 hours, as opposed to every 1-2 hours in Phase 2. It was unclear how many total days each of the interventions were performed.

In Phase 1, the treatment group included 27 knees from 19 patients. The control group for Phase 1 included 21 knees from 17 patients. In Phase 2, the treatment group included 23 knees from 17 patients. The control group for Phase 2 included 34 knees from 23 patients.

The only inclusionary criteria stated were that all patients had a primary TKA with insertion of a Porous-Coated Modular or a Duracon prosthesis, all components were cemented, and Continuous Passive Motion machines were used. There were no exclusionary criteria stated.

Outcome measures: The outcome measures that are most relevant to my clinical question are knee ROM (measured in flexion AROM), edema (circumferential increase measurement of mid-patella and distal thigh), and medication use (morphine equivalent).

Knee ROM and edema were measured at 2-4 days, 7-14 days, and 4-6 weeks post operation. Narcotic use was measured at 0-3 days and 4-7 days post operation. The reliability, intra/inter-rater reliability, MCID, and validity of the outcome measures were not discussed. These outcome measures seem to be the gold standard. However, knee ROM is more commonly measured as flexion and extension PROM.

Study losses: No study losses were reported. There was no intention to treat analysis performed. All subjects were analyzed in the groups to which they were randomized.

Summary of internal validity: The internal validity of this study is fair at best. First of all, there was no blinding. Although the subjects were randomized, there was no assessment as to whether the subjects were similar at baseline. Also, even though most of the outcome measures were the gold standards, their validity and reliability were not addressed. Together, these factors amount to a major threat to internal validity.

Evidence: In Table 1, the mean knee flexion AROM measurements are shown for each group at each interval. According to the authors, the Cryo Cuff group did not have significantly different results from the control group. Due to lack of statistical information (standard deviation), it is impossible to perform my own statistical analysis.

**Table 1:
Mean Knee Flexion AROM (degrees)**

Interval	2-4 Days	7-14 Days	4-6 Weeks
Phase 1			
Control	64	88	106
Cryo Cuff	70	84	103
Phase 2			
Control	88	97	108
Cryo Cuff	80	93	111

In Table 2, the mean knee circumferential increase measurements are shown for each group at each interval. According to the authors, the Cryo Cuff group did not have significantly different results from the control group. Due to lack of statistical information (standard deviation), it is impossible to perform my own statistical analysis.

**Table 2:
Knee Swelling: Mean Circumferential Increase in cm**

	2-4 Days Mid- patella	2-4 Days Distal Thigh	7-14 Days Mid- patella	7-14 Days Distal Thigh	4-6 Weeks Mid- patella	4-6 Weeks Distal Thigh
Phase 1						
Control	2.1	1.6	2.9	3.0	0.6	0.7
Cryo Cuff	1.0	0.8	0.7	0.6	0.3	0.6
Phase 2						
Control	2.0	2.0	0.7	0.6	0.6	1.1
Cryo Cuff	2.3	2.2	0.3	0.6	0.8	1.0

In Table 3, the mean narcotic use measurements are shown for each group at each interval. The authors evaluated unilateral and bilateral TKA patients separately. According to the authors, the Cryo Cuff group did not have significantly different results from the control group. In fact, narcotic use of bilateral TKA patients was more than that of the control group. Due to lack of statistical information (standard deviation), it is impossible to perform my own statistical analysis.

**Table 3
Mean Narcotic Use (Morphine Equivalent)**

	Unilateral 1-3 Days	Bilateral 1-3 Days	Unilateral 4-7 Days	Bilateral 4-7 Days
Phase 1				
Control	86.7	108.4	49.9	58.2
Cryo Cuff	89.2	108.9	132.3	189.1
Phase 2				
Control	100	59.5	115.7	79.6
Cryo Cuff	96.6	66.3	143.4	52.0

Applicability of study results:

Benefits vs. Costs: The Cryo Cuff costs between \$75-\$100 to purchase online as opposed to a few dollars for crushed ice, plastic bags, and ace wrap. Both use about the same amount of therapist and patient time. Neither treatment had adverse effects in this study. An important financial (and health) benefit could have been the reduction of narcotic use, due to the high cost of pharmaceuticals. Based on the results of this study, the costs of Cryo Cuff use outweigh its benefits.

Feasibility of treatment: The use of the Cryo Cuff was described well enough in the study to be reproduced in the clinic. Although this treatment is something that is prescribed by a Physician or Physical Therapist, it can be executed by nursing, therapy aids, and even the patients themselves. Most insurance companies pay for use of the Cryo Cuff (and Game Ready) and the treatment itself is not painful. The patient compliance of the home use of different types of cryo therapy was not addressed in this study. It would be an important factor in the outpatient setting.

Summary of external validity: The poor internal validity of this study compromises the ability to generalize its results to my clinical population. The subjects in this study are similar to the ones in my clinical population except for the fact that TKA surgeries are 15 years more advanced now than at the time of the study.

My clinical question was focused on the use of continuous flow cold therapy (Game Ready) on patients in the outpatient setting/timeframe. In this study, the patients received an older version of the Game Ready without mechanical continuous flow for an unclear amount of days following surgery. The results of this study can be applied to patients following TKA surgery that are receiving some sort of cryo therapy while in the hospital.

Article: Barber, 2000.

Clinical Bottom Line: This study only partially answered my clinical question. The internal and external validity were fair at best. This study addressed the proper intervention comparison (continuous flow cold therapy vs. crushed ice and compression wrap) in the wrong population (ACL repair, not TKA) and time frame (1st week vs. outpatient time frame). Upon reviewing this study, I can say with moderate confidence that the continuous flow cold therapy machine is more effective than crushed ice in increasing knee PROM and decreasing pain (but not vicodin use) in the first week following ACL repair surgery. It is also important to note that the machine is very expensive compared the small amount of insurance reimbursement per PT billing code.

Article PICO:

Patient: 87 patients s/p ACL repair surgery
Intervention: Mechanical continuous flow therapy
Comparison: Crushed Ice
Outcome measures: Pain, ROM, narcotic use

Blinding: The subjects, therapists/nursing, and assessors were not blinded in this study. The fact that the assessors (the only people who could be blinded in this type of study) were not blinded could be a threat to internal validity.

Controls: The control group received crushed ice that was held onto the knee by an elastic bandage. I believe that this was an appropriate control group because this was the most commonly used (and paid for by insurance) cryo therapy intervention used at the time the study was performed.

Randomization: The subjects were sampled by convenience and were not randomized. However, all patients had similar baseline knee ROM measurements of at least (0-0-120) with no effusion due to pre-surgical rehab.

Study: This study was a convenience sampled controlled trial design. There were 87 patients (52 treatment, 35 control) at an average age of 33 years (range: 15-53) in the study.

The inclusionary criteria for the subjects chosen were the ability to speak/understand English, have undergone an arthroscopically assisted ACL reconstruction by patellar tendon auto graft, complete the 2 hour evaluation while at the surgicenter, be available for follow up phone evaluations at certain time intervals, comply with the therapeutic regimen, and agree to complete and return a postsurgical diary.

The exclusionary criteria allergies to hydrocodone bitartrate with acetaminophen, oxycodone hydrochloride with acetaminophen, or acetaminophen with codeine phosphate; a significant coexisting injury or illness that contraindicated administration of cold therapy; any serious concomitant injury; or undergoing multiple ligament reconstructions or revision ACL surgery.

The treatment and control groups both received physical therapy for 6 weeks prior and achieved knee ROM measurements of at least (0-0-120) with no effusion. All subjects were instructed to weight bear as tolerated with crutches following surgery. A home exercise program was given to all subjects with knee extension exercises that included prone knee hangs and bridging exercises.

All subjects were given specific medication management instructions that included taking pain medication only after the perception of pain and not preemptively. Both inventions were used constantly for the first three post surgical days. After that, patients were instructed to use their cold modality whenever using the Continuous Passive Motion machine and additionally as desired. The CPM machine was used with all patients for 6-8 hours per day for an unstated amount of days.

The control group received crushed ice that was held onto the knee by an elastic bandage. They were instructed to change the ice and ice bag every time the ice melted. The treatment group received a constant flow portable cold therapy unit that has a reservoir where ice and water are placed. A continuous flow of water (35*-50* F) moved through an aircast-like bladder contained within the patient's sterile dressing.

Outcome measures: The outcome measures that are most relevant to my clinical question are pain (Visual Analog Scale and Likert Categorical Pain Scale), ROM, and Vicodin use. Both VAS and Likert pain scores were recorded in the surgicenter and by phone at 1 hour, 2 hours, 8 hours, and once a day for days 2-6. Knee passive range of motion was measured at the 1-week post operation check up. A daily total of vicodin use was recorded for days 1-6.

The reliability of the outcomes measures was not addressed. The authors did not cite intra- or inter-rater reliability from other studies or report their own. The authors did not discuss the validity of the study's outcome measures. The VAS for pain and goniometry from PROM are the gold standards of measurement for their respective measures. It is unclear if the measurement of Vicodin use is the gold standard for measuring pain medication use. The authors did not discuss the minimal clinically important differences (MCID) for these outcome measures.

Study losses: All subjects completed all follow up assessments and no study losses were reported. All subjects received monetary compensation for completing the study. No intention-to-treat analysis was performed. All subjects were analyzed in the groups to which they were divided.

Summary of internal validity: The internal validity of this study is fair. The outcome measures are generally valid ones and there were no study losses. However, there was no randomization, blinding, or assessment of subjects at baseline (only general PROM criteria). Together, these pose a moderate threat to the internal validity of the study because the differences within subjects and assessors weren't accounted for.

Evidence: In Table 4, mean pain scores for the VAS and Likert scales are shown. A Fischer's Exact Test and Mandel Haentszel chi square test with $P < .05$ were calculated by the authors with Statistical Analysis System version 6.09. The mean VAS score for the continuous flow group had a statistically significant difference only at the 8 hours and 2 days assessment points, but was never higher than the continuous flow group. The Likert categorical pain scores showed a statically significant decrease in pain with the continuous flow group at all assessment points.

**Table 4
Mean Pain Scores**

	Hour 1	Hour 2	Hour 8	Day 2	Day 3	Day 4	Day 5	Day 6
VAS (0-10)								
Crushed Ice	4.51	4.06	5.49	7.32	5.91	5.03	4.88	4.45
Continuous Flow	3.71	3.61	4.10	5.61	5.04	4.55	4.29	4.33
Likert (0-10)								
Crushed Ice	2.47	2.2	2.57	2.94	2.6	2.35	2.49	2.21
Continuous Flow	1.08	1	1.18	1.76	1.65	1.31	1.42	1.31

In Table 5, the mean daily vicodin use is given for each group. A Student's t-test with $P < .05$ was calculated by the authors with Statistical Analysis System version 6.09. Percocet was also taken by subjects earlier on in the study and there was no significant difference reported between the two groups. Vicodin use was statistically shown to be significantly greater in the crushed ice group on days 1 and 2. However, vicodin use was greater in the continuous flow group on days 4-6.

Table 5
Mean Daily Vicodin Use (units not stated)

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Crushed Ice	2.26	2.7	2.74	1.51	1.51	1.4
Continuous Flow	0.86	1.49	2.06	1.9	2.12	2.47

In Table 6 and 7, the results of the 1-week post-operative PROM measurements are given. A Student's t-test with $P < .05$ was calculated by the authors with Statistical Analysis System version 6.09. There was no significant difference found between groups for the amount of subjects that did not achieve full extension by 1 week. However, the knee flexion PROM at 1 week was found to be significantly greater in the continuous flow group at $P = .03$.

Table 6
Knee Flexion ROM scores (degrees) at 1 Week Post-Op

	Mean	Range of all Subjects
Crushed Ice	77	(30-124)
Continuous Flow	88	(48-155)

Table 7
Percentage of Subjects That Did Not Regain Full Knee Extension at 1-Week Post-Op

	Greater/Equal to 5 degrees	Greater/Equal to 10 Degrees
Crushed Ice	74	40
Continuous Flow	52	25

Other outcome measures that were not part of my clinical question included subject reported tolerance and performance of cold therapy measured by categorical scales, amount of time spent using the CPM, amount of time spent doing prone hangs, and the amount of (PRN) time the subjects chose to use the cold therapy from days 4-6. Subjects in the continuous flow group were statistically found to use their cold modality for a significantly higher amount of hours during the (PRN) days 4-6. No other significant outcomes loosely related to my clinical question were reported.

Applicability of study results:

Benefits vs. Costs: The game ready machine will cost a clinic around \$2,500 for the machine itself, and around \$400 per cuff (different for each body part). It is often temporarily rented to patients for a couple weeks following surgery and is paid for by insurance. Physical therapists can bill for the use of this device in the clinic. A “vasopneumatic device” billing code is around \$13 (was \$24).

The use of the continuous flow therapy machine requires the around the same amount of time as crushed ice for therapists and patients. The only difference would be the time to train the patient as needed for home use. No adverse effects were reported for either intervention.

Both groups received that same amount of intervention time, except for days 4-6 when they were allowed to use the cold modality as much or as little as they would like. The costs for the intervention groups were not equal. The crushed ice in a plastic sack is very inexpensive. The cost-effectiveness of the continuous flow cold therapy machine will depend on how many patients you will be using it on and how busy your clinic is. It is certainly a significant cost up front.

Feasibility of treatment: The procedures were described well enough to be easily reproduced. The requirements of equipment, clinician expertise, and time are realistically available in the outpatient PT setting. The continuous flow cold therapy treatment met the general guidelines for being paid for by insurance.

This treatment is also very feasible for patients. Patients were required to use this treatment at home in the study. However, the use of the treatment in the outpatient setting does not require home use. Also, the treatment can be uncomfortable, but was reported in this study to be generally more tolerable than crushed ice.

Summary of external validity: The threats to internal validity definitely compromise the ability to generalize the study’s results. The subject sample of ACL repair patients (teens to 50 y/o) is only slightly similar to my clinical population of TKA patients (usually >50). The results of this study can be extrapolated to the general population of patients undergoing an ACL repair.

Synthesis/Discussion

It is difficult to speak in absolutes when applying the results of these studies to my clinical question. This is due to the poor/fair study designs of both studies. Another reason would be the difference between interventions and patient populations between the two groups. The influence of cold therapy on pain, ROM, and edema is very important when returning a TKA patient to normal functional pain-free ambulation. As I stated in my article justification, I wanted to investigate the cost effectiveness of using the expensive Game Ready device instead of crushed ice with a compression wrap with TKA patients within the outpatient therapy time frame.

By choosing the combination of these two articles, I hoped to answer each component of my clinical question as completely as possible. Unfortunately, there are no articles that use the continuous flow cold therapy device to treat patients following TKA surgery. Together, these studies gave me only a few pieces to answer my clinical question.