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The Efficacy of Cryotherapy and Dynamic Compression Compared to Ice and Static Compression Following Total Knee Arthroplasty

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Abstract

Purpose: The purpose of this research review is to investigate the efficacy of cryotherapy with dynamic intermittent compression (CDIC) compared to less advanced methods of cryotherapy, after total knee arthroplasty (TKA).

Background: The use of cryotherapy after surgery is a common and even standard of practice to help mitigate the side effects post-operatively. Some of these side effects include inflammation, pain, swelling, and stiffness; all of which, if not controlled, can influence recovery and have a detrimental effect on healing and returning to prior level of function. Currently there several different methods and treatment options when it comes to cryotherapy. There has been a steady increase in the number of TKAs each year. The push for patients to leave the hospital and return to work or sport faster is driving the development of better, more advanced modalities to speed up recovery. There are many therapeutic devices that claim to provide a better, faster recovery by delivering continuous cooling and intermittent pneumatic compression that mimics the body's muscular pump. While the benefits of cryotherapy post-operatively have been demonstrated in research, the most effective cryotherapy method is still debated and there is currently limited research investigating the efficacy of more advanced commercial devices.

Case Description: The patient is a 68-year-old female presenting to the orthopedic outpatient clinic two days status post right TKA with pain, reduced range of motion, and increased swelling. She had a left TKA two years prior, and had a difficult time controlling her pain and swelling due to her limited tolerance of narcotics and ice, leading to a delayed return of range of motion and functional activities.

Methods: A literature review was conducted and numerous databases were searched to find research investigating the efficacy of CDIC devices compared less advanced cryotherapy methods.

Discussion: Upon literature review of current evidence, there is very limited high quality and consistent evidence that supports the use and the benefits of a CDIC device over standard ice and compression. With the inconsistency in results among current research and limited use of objective measures, it is difficult to draw a strict conclusion on whether the benefits outweigh the cost. Based on the research, CDIC devices are not seen to be superior to a standard ice bag with compression, and in some studies are seen to be less effective. Considering the cost of a CDIC device and its limited benefits, this method may not be appropriate for the majority of the patient population following TKA.

Background

Total knee arthroplasty (TKA) is one of the most common joint replacement surgeries. According to the American Academy of Orthopaedic Surgeons, approximately 581,000 TKAs are performed each year. That number is expected to reach almost 3.5 million by 2030 (Bell, 2011). The limiting factors that generally lead a person to undergo TKA are pain and decreased functional activity. The most common cause of pain and limited function is osteoarthritis, which is a general wear and tear that occurs in joints as a person ages. Osteoarthritis is a primary source of disability in the United States and the knee joint is the most common joint to develop osteoarthritis (Mizner et al., 2011). Patient age, radiographic severity of osteoarthritis, and severity of symptoms including response to other treatment modalities are typically considered the three key factors in selecting patients for TKA (Chang et al., 2010). After surgery, some common limitations include decreased range of motion, increased pain, increased edema, decreased strength especially in the quadriceps, decreased patellar motion, and decreased functional activity. All of these impairments will usually improve or resolve over time and with skilled physical therapy for a patient without complications. If these impairments are not addressed, function is typically greatly affected. Recovery can take time, hard work, and can be uncomfortable. The overall goal of physical therapy is return a patient to their prior level of function, or potentially better than their prior level of function, in a safe and efficient manner.

Objectively measuring impairments is imperative in a clinical setting to assess the patient's recovery and the effectiveness of treatment. Some of the most common outcome measures used to assess function following a TKA include range of motion, strength, patient perceived pain, and functional performance. These outcome measures help identify persistent impairments and functional limitations compared to healthy adults (Bade et al., 2010). Knee

stiffness, swelling, and pain are very common following TKA. They are also very common limiting factors in return of function. In order to reduce impairments and improve functional outcomes of the patient, the emphasis of physical therapy in the first few weeks is on edema management, improving range of motion, and strengthening (Meier et al., 2008).

There are numerous treatment options and modalities implemented following a TKA, to improve the outcomes of the patient. Pain is often severe in the early postoperative period, impeding rehabilitation. Mobilization requires pain control, but the side effects associated with narcotics, such as nausea, vomiting, sedation, pruritus, hypotension, and respiratory depression can limit activity, result in longer hospital stays, increase morbidity, and reduce patients' satisfaction (Trueblood A., Manning D., 2007). Cryotherapy and compression are some of the most commonly used modalities to address pain and swelling following TKA. Compression is thought to decrease edema by increasing hydrostatic pressure, thereby reducing the outflow of fluid into the interstitial space. The use of cryotherapy, more specifically ice packs, is a widely utilized and recommended modality after tissue injury, especially injury due to surgical intervention. Cryotherapy has been shown to be an effective method of decreasing pain, inflammation, and edema, particularly in the acute phase of healing.

Cryotherapy leads to vasoconstriction at the cellular level, decreases tissue metabolism, and blood flow. Capillary permeability is also decreased, and the release of inflammatory mediators and prostaglandin synthesis are inhibited, all of which play a role in acute inflammation and edema. As the temperature of peripheral nerves decreases, a corresponding decrease is seen in nerve conduction velocity across the nerve synapse, thus elevating the pain threshold in nerve fibers; A-delta fibers (pain transmitting fibers) having the greatest decrease in conduction velocity (Cameron, M., 2013).

While, there are many benefits to cryotherapy, a therapeutic level of cooling must be reached to see the effects of this modality. A therapeutic level is reached by the temperature of the cooling method and the duration it is placed on the skin. According to Cameron (2013), vasoconstriction will persist if the duration of the cold application is less than 15-20 minutes with an hour apart from the next application. Significantly lower blood flow occurs if a regimen of two repetitions of 10 minutes on and 10 minutes off is implemented after the initial 20-minute application. Nerve conduction velocity is also decreased for up to 30 minutes after 20 minutes of cooling. There have been a number of published studies that investigated the ability of different modalities to reduce tissue temperature. They conclude that the modality that produces lower tissue temperature attains higher therapeutic efficacy. However, tissue must be cooled to a certain level before any therapeutic effects occur. Cold-induced analgesia begins after the localized skin surface temperature lowers to approximately 13.6°C. To minimize cellular metabolic rate, skin surface and tissue temperature should be maintained near 10°C (Kanlayanaphotporn, R., Janwantanakul, P., 2005).

Due to these benefits, the industry of cryotherapy has, over the last few decades, been exploring better, faster, and more effective ways to apply cryotherapy. The individual and combined effectiveness on these limiting factors has been debated in previous research. One systematic review by Markert (2011) looked at ten research studies and one meta-analysis on the effects of cryotherapy on patients post TKA. Six of the studies showed significantly lower pain scores in the cold compression group than in a control group. Four found no differences in pain scores between the groups. Overall, most of the studies showed no difference in range of motion of the operative knee after the application of cold compression. A decrease in swelling and a decrease in blood loss was seen within the cold compression group, although not statistically

significant. A randomized controlled trial by Bech et al (2015) looked at the comparative effectiveness of consistent cooling using an icing device versus intermittent cooling using an ice bag and found no significant difference between the effects of intermittent cooling with an ice bag and those of consistent cooling using a device with respect to pain, blood loss, nausea or vomiting, self-reported function, passive range of motion, or length of stay after TKA . Another systematic review by Adie et al (2012) looked at eleven randomized trials and one controlled clinical trial, with very low quality evidence, and found that cryotherapy has a small benefit on blood loss; however, not clinically significant. There was also very low quality evidence from four trials that cryotherapy improved visual analogue score pain at 48 hours, with the benefit not being clinically significant. There was low quality evidence from two trials for improved range of motion at discharge, but this benefit may not be clinically significant. No significant benefits were found for analgesia use, swelling or length of stay. A study comparing the use of a cold compression dressing to compression alone looked at blood loss, range of movement, pain scores and need for analgesia (Gibbons et al., 2001). No difference was found between the groups except for less blood loss in the surgical drains in the cold compression group. Based on previous research there does not appear to be an inherent difference in outcomes between ice, compression, or a cryo-compressive device. While the P/RICE (protection, rest, ice, compression, and elevation) principle has been a standard of care following surgical recovery for decades, with all the new technology out there, the following question is raised: Is there a better, faster, safer way to recover?

While an ice bag with or without some form of compression wrap is a common standard of practice, there has been further exploration into more optimal cooling techniques: applying more standardization over temperature, time, and compression. New devices that apply

cryotherapy with dynamic intermittent compression (CDIC) have been coming into the market for the last few years. These high-tech devices have been gaining popularity amongst cryotherapy devices due to the representation from international athletes and claims on improved recovery. The CDIC systems have adjustable temperature controls, with temperatures ranging from 5-13^{o}C, continuously circulating water, and adjustable cyclical pneumatic (air) compression. The utilization of pneumatic compression mimics the natural muscle pump action of the body to reduce edema. It has a conform wrap that provides better surface contact and thus more effective cooling, and avoids the pain that can accompany ice treatments (CoolSystems, Inc. 2017). The Game Ready® system claims to be the only product on the market that provides rhythmic cyclical compression and controllable cold therapy, the combination of which claims to help bodies heal faster. The system purports to provide circumferential cooling effects comparable to those of a slush bucket, and compression comparable to an ice bag with compression, while avoiding the side effects of the intense cold pain.

Although applying a bag of ice is a common method of postoperative cryotherapy, the frequency, intensity, and duration of application vary, which may contribute to suboptimal care for patients. Moreover, this method of cooling carries a risk of precipitating skin and nerve damage (Bech et al., 2015). With the lack of consensus using cryotherapy, ice, or compression following TKA, a CDIC device may be a reasonable alternative to the current standard of care. The goal of this study is to investigate current research regarding the efficacy of a CDIC device compared to ice and static compression in regards to reducing edema, inflammation, pain, improving functional outcomes, and increasing range of motion post TKA. This article also aims to offer more researched based evidence, to provide all parties involved with more information on cryotherapy with compression. This will help patients receive the most effective care

regarding the utilization of cryotherapy modalities, as well as give the healthcare team more evidence on the outcomes of different cryotherapy methods.

Case Description

The patient that inspired this PICO question was a 68 year-old female who was returning to work as a school principal three weeks after her right TKA. She had a left TKA two years prior, and had a difficult time controlling her pain and swelling at that time, leading to a delayed return of range of motion and functional activity. She presented to the orthopedic outpatient clinic two days status post TKA using a front wheeled walker, with 7/10 pain, reduced knee range of motion, and increased knee swelling, all of which were limiting her functional activity. The patient reported disliking narcotics and ice. This led the therapist to question whether a dynamic intermittent cryo-compressive device would be more beneficial than ice and compression in gating pain and limiting swelling.

Methods

The purpose of this literature review was to answer the proposed PICO question: In a patient following a TKA, what is the efficacy of a CDIC device compared to ice and static compression in regards to reducing edema, inflammation, pain, improving functional outcomes, and increasing range of motion? The databases searched included PubMed, CINAHL, PTNow, Web of Knowledge, PEDRO, and SPORTDiscus. Search terms used for the literature review included: “pneumatic compression with cold AND post surgical”, “total knee arthroplasty”, “ice AND dynamic compression”, “cryotherapy”, “edema AND pain”. Succeeding a review of the titles and abstracts, eight articles were selected to answer the research question. These eight articles were reviewed, analyzed, and compared to the research question proposed. An analysis of the search is shown in Figure 1: Articles Included and Excluded for Analysis. Article

summaries can be found in Table 1: Article Summaries as well as in Appendix A. Article analysis are located in Appendix B.

Figure 1. Part I Methods: Articles Included and Excluded for Analysis

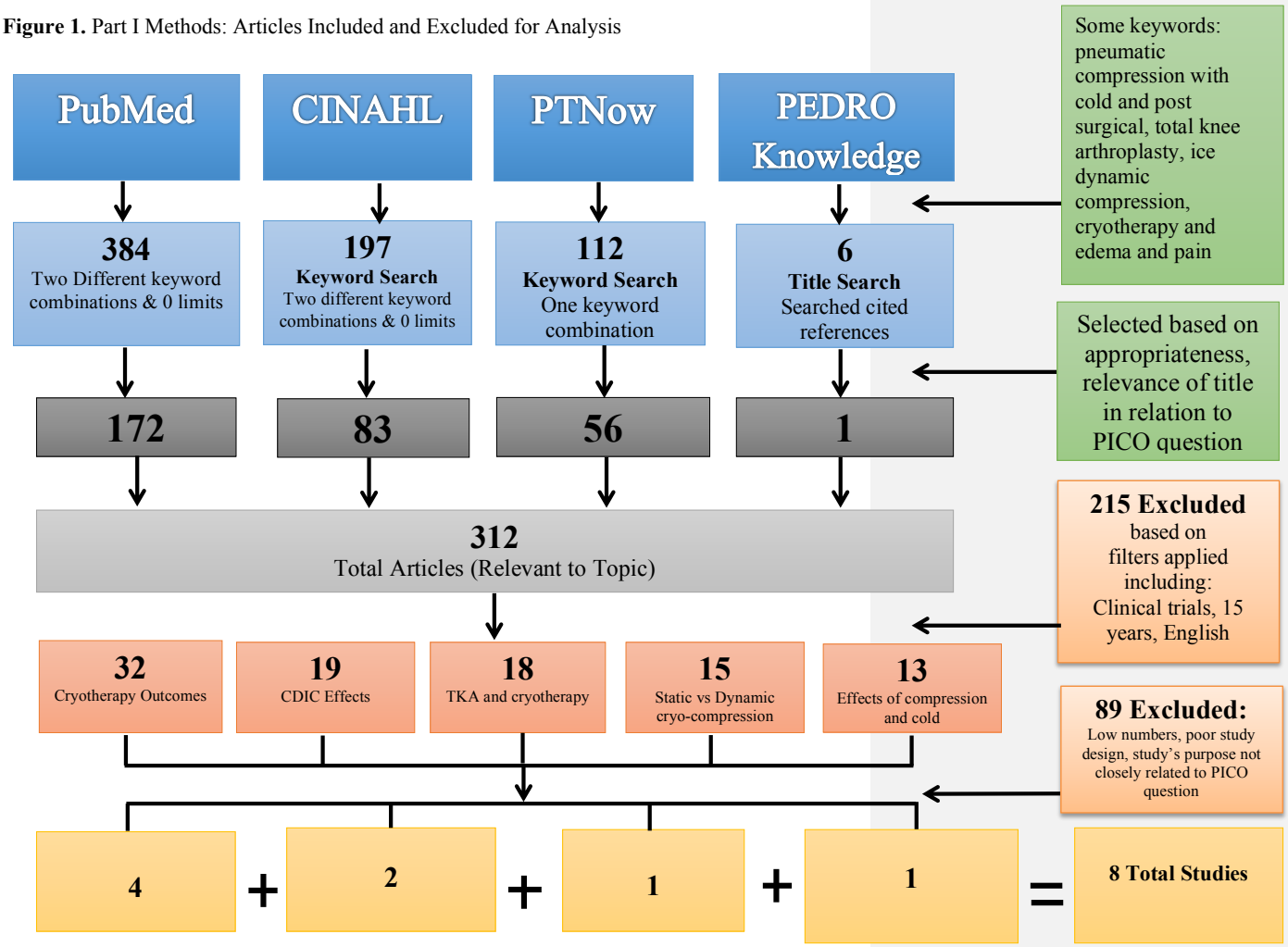

Table 4. Part I Results / Article Summaries

	Study & Origin	Oxford Level of Evidence	Pedro Score	Purpose of Study	Outcome Measures	Results	Accept Results to Answer Clinical Question
1	Hawkins J., et al. (2011) USA			To compare the cooling abilities of the Game Ready® Injury Treatment System, ice with compression, and a slush bucket.	-Average sinus tarsi tissue -Average sinus tarsi skin temperatures	-Significantly colder tissue and skin temperatures for the ice with compression and slush bucket treatments were than the GR treatment (p<0.001), but did not differ from one another (p=0.48 and 0.49 respectively). -Significant temperature differences for all three modalities (p<0.001) both in the tissue and on the skin following the post treatment period, with GR being the least cold, followed by ice with compression, and then the slush bucket.	Yes
2	Holwerda S.W., et al. (2013) USA			To investigate the cardiovascular responses and tissue temperature decreases of common therapeutic applications of cryotherapy, including ice bag/elastic wrap and the continuous circulating water and intermittent pneumatic compression provided by the Game Ready system®.	-T_{IM} -T_{SF} -T_{ORAL} -MAP -HR -RPP -FBF -FVC	-Significantly cooler temperatures in muscle were seen when using ice compared to the GR -Significantly cooler temperatures in muscle were seen on medium and high compression settings than GR without compression (P < 0.05). -Significant decrease in forearm blood flow and forearm vascular conductance after baseline (P < 0.05) but there were no differences between treatments. - Peak intramuscular temperature changes from baseline were –14 ± 2°C (ice), –11 ± 6°C (GR_{HIGH}), –10 ± 5°C (GR_{MED}), and –7 ± 3°C (GR_{NO}).	Yes
				To compare the effect of CC vs. ice	-VAS average pain -VAS worst pain	- No significant differences were found in average scores for the SF-12 physical subscore	Yes

3	Kraeutler M.J., et al. (2015) USA			on pain during the immediate postoperative week in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression.	-MED -SF-12	for the CC and IW groups, (P=.93). -No significant differences were found in average pain, worst pain, or MED on days 0 to 7. - CC group used a higher MED every day, difference was not statistically significant. -The average total MED during postoperative days 0 to 7 was also higher in the CC group, but was not statistically significant (P=.28).	
4	Leegwater N.C., et al. (2012) Netherlands			To study the effect of intermittent cryo-compression therapy on pain scores, analgesic use, and wound discharge. In addition, the feasibility of the system was assessed together with patient satisfaction following elective THA	-Blood loss peroperative (mL) -Hemoglobin OK+1 – preop -Hemoglobin OK+3 – preop -Hemoglobin OK+3 - OK+1 -Wound discharge -Total oramorph usage -Days of leakage -Total admittance time (days) -Patient Questionnaire Game Ready® experience	-Significantly smaller decline in hemoglobin level on post-op day 1 in the intervention group (p= 0.027). -No significant differences were found in total oramorph usage, but in the control group usage was 100 mg compared to 84.7 mg in the intervention group (p= 0.593). -Significantly lower discharge rates in the intervention group (p= 0.053). -No significant differences were found in the mean total hospital stay.	Yes
5	Murgier J., et al. (2017) France			To assess the efficacy of cryotherapy with dynamic intermittent compression(CDIC) in relieving post-op pain, decreasing blood loss, and improving functional scores	-Total blood loss -Hemoglobin and hematocrit levels -Transfusion volume and rate ([RCC] units) -Pain on postoperative day 3 -Functional outcomes based on the Oxford score -Number of complications recorded	-Significantly lower total blood loss in the CDIC group than in the control group (P < .05). -Significantly lower transfusion rate in the CDIC group (P < .05) -Significantly lower mean lowest hemoglobin level in the control group (P < .005). -Significantly lower pain at rest on day 3 in the CDIC group than in the control group (P < .05). -No statistically significant difference in cumulative morphine intake at day 5 was seen between groups. - No statistically significant difference in the	Yes

				after revision total knee arthroplasty.		Oxford functional score at 6 months postoperative was seen between groups.	
6	Murgier J., et al. (2014) France			To compare the efficacy of these two compression modalities combined with cryotherapy in relieving postoperative pain and restoring range of knee motion after ligament reconstruction surgery.	-VAS pain score -Consumption of analgesics -Range of knee motion	- No statistically significant difference in the mean VAS pain score (P = 0.3). Significant increase in mean range of knee flexion at hospital discharge for the intervention group (P = 0.0015). -Significantly lower Tramadol consumption in the CDIC group (P = 0.023). -None of the patients in the CDIC group required step 3 analgesics. In contrast, patients in the CSPC group had a significant mean morphine consumption (P < 0.05)	Yes
7	Su E.P., et al. (2012) USA		4/10	To evaluate if 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	-Six minute walk test (meters) -TUG (seconds) -VAS -Flexion (°) -Extension (°) -Satisfaction survey	-Significantly lower narcotic consumption in the treatment group compared with the control group at up to two weeks postop, ($p < 0.05$). -No difference in the total amount of narcotics consumed amongst the two groups between two and six weeks, - A trend toward a greater distance walked in the 6MWT in the treatment group ($p = 0.13$) at six weeks. -Significant difference in satisfaction, with greater satisfaction in the treatment group ($p < 0.0001$). -No difference in ROM, TUG, VAS, or knee girth at six weeks.	Yes

8	Waterman B., et al. (2012) USA			To evaluate and compare the effectiveness of cryotherapy with or without intermittent pneumatic compression after ACL reconstruction, focusing on postoperative edema, pain, and patient- reported outcome measures.	- VAS -Short Form-36 -SANE -Lysholm scores -Medication usage -Circumferential measurements (cm)	-Significant discontinuation of pain medicine in treatment compared to control (p= 0.0008). -No statistically significant differences between or within the two groups across any time intervals for circumferential knee measurements. -No statistically significant differences in comparison of absolute VAS values between groups at all postoperative points. - Significant improvements in VAS relative to the preoperative measurement in the CC group at postoperative week 2 (p=0.023) and week 6 ($p < 0.0001$). -No statistically significant difference in Subjective Patient Outcome Scores were detected between the C and the CC groups at all time intervals. -No statistically significant difference average SANE scores. However, scores were higher in the cooling compression group at 1, 2, and 6 weeks postoperatively when compared with the C group.	Yes

Abbreviations

6MWT: Six Minute Walk Test, C: Control, CC: Compressive Cryotherapy, CDIC: Cryotherapy with Dynamic Intermittent Compression, CSPC: Cryotherapy and Static Permanent Compression, FBF: Forearm Blood Flow, FVC: Forearm Vascular Conductance, GR: Game Ready®, HR: Heart Rate, MAP: Mean Arterial Pressure, MED: Morphine Equivalent Dosage, RCC: Red Cell Concentrate, ROM: Range of Motion, RPP: Rate Pressure Product, SANE: Single assessment numerical evaluation, SF-12: Modified version of the acute 12- Item Short Form Health Survey, T_{IM}: Thermocouple (Intramuscular), T_{ORAL}: Thermocouple (Oral), T_{SF}: Thermocouple (Skin Surface), TUG: Timed Up and Go, VAS: Visual Analog Scale

Discussion

There is conflicting evidence regarding the efficacy of a CDIC device as compared to ice/compression. Based on the available evidence, there is little to no significant difference in increasing range of motion, decreasing edema, and improving functional outcome scores between the two interventions. Two studies found that ice bags provided more skin and intramuscular cooling when compared to CDIC devices (Hawkins et al, 2012; Holwerda et al,2013). In two studies, participants reported a more comfortable experience when using the CDIC device (Leegwater et al, 2012; Su et al, 2012). Three studies found a significant difference in narcotic consumption when using a CDIC device (Murgier & Cassard, 2014; Su et al, 2012; Waterman et al, 2011). Three studies did not find a significant difference in narcotic consumption using the CDIC device (Kraeutler et al, 2015; Leegwater et al, 2012; Murgier et al, 2017;). Due to the conflicting evidence, the low quality of evidence in the research and the inability to blind the participants,it is difficult to determine if similar effects would be seen in the clinic. Therefore, the results need to be considered with caution. CDIC devices might be appropriate for a population who does not tolerate narcotics well, or who have high amounts of pain post-operatively.

Su and Gerlinger (2012) found the test group using a CDIC device to have a greater decrease in pain over time, and more CDIC subjects were able to perform complex weight-bearing physical activities over the course of their episode of care. However, this article was an interim analysis and only looked at a small percentage of the subject pool. When analyzing the research study in its entirety, the researchers found no significant difference between the test and the control groups in regards to knee girth, range of motion, or functional outcome measures. There was statistically significantly lower amount of morphine equivalents used by the cryo-

pneumatic group, and patient satisfaction was significantly higher in the CDIC device group with patients expressing a better rate of pain control and relief of stiffness with the device versus ice. However, there was no blinding of participants, so the placebo effect could have played a role in the perception of pain. Therefore, the interpretation of these results need to be used with caution. Murgier et al. (2017) looked at patient outcomes following a revision total knee arthroplasty, and found that patients in the CDIC group had lower total blood loss than patients in the control group. Pain at rest on day three was lower in the CDIC group than in the control group. However, the procedures were conducted in a specialized TKA surgery unit that used advanced pain control methods. There was no statistically significant difference in range of motion, Visual Analog Scale scores, Timed Up-and-Go scores, or Six-Minute Walk Test scores between the two groups. Both of the articles found some benefits in using a CDIC including decreased pain, lower blood loss, and the ability to perform activity. The lack of blinding, a lack of standardization of treatment for the control group, and the variability in the results, especially for pain, between the two articles gives some pause and consideration to the claims made by the CDIC systems.

The current research on the efficacy in using CDIC devices post TKA is minimal and the evidence is very low quality. In expanding the research terms, additional articles were found and reviewed. These articles looked at other types of surgeries to determine the effect of a using a CDIC device compared to a control. The articles were included due to the limited research on the efficacy of CDIC following a TKA and the general assumption that acute tissue healing is relatively the same following other types of surgical intervention. Two articles investigated the outcomes following anterior cruciate ligament reconstruction using a CDIC compared to a control (Waterman et al, 2012; Murgier & Cassard, 2014). Both articles found short term pain relief in the CDIC groups. Murgier and Cassard (2014) also found an improvement in knee range

of motion in the CDIC group. The sample size in both research studies was small, which made detecting statistically significant difference impossible. This limits the power of the results. The participants in the research by Waterman et al (2012) were of a young active military population, making the study fairly homogenous. This limits the external validity of the study, therefore the results may not observed within the general population. The surgery performed was also very different than TKA, further limiting the applicability of the results. A study investigating the effect of CDIC intervention compared to ice alone following rotator cuff repair found no significant benefit of the CDIC device over ice in acute pain (Kraeutler et al., 2015). However, pain and total medication usage were the only outcome measures assessed and treatment was not observed or standardized, potentially limiting the eternal validity. Without the assessment of other outcome measures such as range of motion or edema, it is hard to deduce the overall effectiveness of the CDIC device. This makes it difficult to make an informed decision on the clinical clout of this device over ice alone. In a study comparing CDIC devices with no treatment following hip arthroplasty, a trend towards lower morphine use and shorter hospital stay and less blood loss was indicated, but there was no difference in post-operative pain scores (Leegwater et al., 2012). Once again, no other functional outcome measures were assessed, making it difficult to draw an objective conclusion. Furthermore, the control group did not receive any other modality, such as ice and/or compression, to help reduce the effects of surgery besides pain medicine. The study design of an intervention compared to no treatment can bias the perception of the effectiveness of the treatment.

There was a lack of blinding of participants, therapists, and researchers in a majority of the studies analyzed in this literature review. Due to the nature of the intervention, it was virtually impossible to blind the participants to what treatment they were receiving. This

Comment [TE1]: Are you still talking about the Leegwater study in this paragraph?
I am talking about the majority of studies that I analyzed
Okay, I added “in this literature review” for clarification.

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knowledge could potentially bias the results, creating a placebo effect in the amount of pain perceived. This effect is concerning especially when one or more of the outcome measures was a subjective questionnaire related to pain perception or overall experience. The postoperative medical staff in some of the research reviewed was also not blinded to the groups. This could have influenced how each group was managed and how specific measures were assessed. Patients aware of the treatment they are receiving can affect how they view their symptoms, their perception of the quality of the treatment they are receiving, and can lead to an imbalance between the treatment group and the control group. Not blinding the participants may decrease the ability to equally compare the outcomes between the treatment and control groups, which can lead to a greater potential for bias of the treatment effects. Without blinding participants, the ability to limit bias and strengthen validity are greatly impacted. This lowers the quality of research and directly effects how the results are interpreted.

The small sample sizes in the majority of the studies affects the research quality as well as the internal and external validity, and limits the power of the results. The small samples also impact the ability to determine if there really was a significant difference seen between groups. Therefore, it is difficult to determine how effective the treatments were in respect to the outcomes measured, and difficult to draw a conclusion as to whether CDIC systems are as effective as the claims made by the company. Due to the inability to blind, the small sample sizes, the conflicting results in the evidence, the low level of evidence, and the limited outcome measures assessed, research regarding the efficacy of a CDIC device compared to ice and compression, ice alone, or a device using static compression and ice postoperative, and more specifically post TKA, is very limited and is of relatively low quality.

There is a need for more research on the efficacy of CDIC devices on postoperative outcomes following a TKA. Due to the cost and the publicity of these devices, more studies looking at functional outcomes like edema, range of motion, and Lower Extremity Functional Scale specifically following TKA would be valuable to patients and physical therapists. Larger sample sizes, a stronger implementation of blinding researchers and postoperative care providers, as well as fewer subjective outcomes would better control for bias and weak validity.

Conclusion

The research analyzed concerning the efficacy of a CDIC compared to ice alone, ice and compression, or a static ice and compression device is limited and of relatively low quality. The consensus among the studies is that there are little to no differences in outcomes when CDIC is compared to another icing method. While there are no adverse effects for using a CDIC device versus another method of icing, the benefits are minimal and do not necessarily justify the cost and potential inconveniences that come along with this advanced cryotherapy. When considering all patient populations, a CDIC device may have more effective results for patients who have a reduced tolerance to cold when using a standard ice bag.

Due to the lack of high quality research and conclusive evidence, insurance companies typically do not cover these devices. According to Blue Cross Insurance Policy (2014), active and passive cooling devices are considered not medically necessary. Based on new studies with active cryotherapy/compression devices and limited evidence of an improvement in clinical outcomes, combination active cooling and compression (cryopneumatic) devices are considered investigational**.** Additional research is needed to permit conclusions regarding the effect of this technology with greater certainty. Moda Healthcare (2017) states that available scientific literature is insufficient to document that the use of active cooling devices is associated

with a greater benefit as compared to least costly standard ice packs or passive cooling devices. They consider active cooling devices experimental and investigational. Similarly, Blue Cross and Blue Shield of Rhode Island (2013) states that Medicare indicates cooling therapy items do not fit the definition of reasonable and necessary and are therefore not covered. Multiple health insurance sources indicate that there is no medical necessity of cold therapy products like CDIC devices due to low quality evidence and limited improved outcomes. These devices are not cheap for a patient to rent or for a clinic to buy. With little to no coverage or reimbursement from insurance, most of the cost will be out of pocket. This is something to consider before recommending and utilizing this type of device.

Well-designed randomized controlled trials are required to improve the quality of the evidence for this research topic. While CDIC devices are popular in the recovery industry, the low level evidence and limited research does not necessarily support a change in the standard of practice (ice bags) in post-operative recovery. The limited benefits seen in the research when using a CDIC compared to ice does not justify their cost to benefit ratio unless working with a very select population. Based on the current research and clinical knowledge, a CDIC device does not provide superior benefits in post-operative recovery over a standard ice bag. Even though there is limited research and variable results among the studies, a standard ice bag remains to be the most cost effective and the most convenient method the market has to offer. It is also the most effective way to reduce tissue temperatures, allowing for the full benefits that cryotherapy offers in post-operative recovery.

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Appendix A: Article Summaries

Hawkins, J., Shurtz, J., & Spears, C. (2012). Traditional cryotherapy treatments are more effective than game ready® on medium setting at decreasing sinus tarsi tissue temperatures in uninjured subjects. *Journal of Athletic Enhancement*, *1*(2). doi:10.4172/2324-9080.1000101
Level of Evidence: Oxford 3b, PEDRO N/A

Purpose: To compare the cooling abilities of the Game Ready® Injury Treatment System, ice with compression, and a slush bucket.

Methods: A cross-sectional group comparison was done on 20 healthy college-aged subjects' sinus tarsi tissue and skin tissue. To compare tissue temperature using ice with compression, a slush bucket, and Game Ready® was used during a 20-minute treatment. All participants had a thermocouple inserted 2 mm into their sinus tarsi and an additional thermocouple taped to the skin within 5 mm of the same location. Temperature was recorded 10 minutes after insertion (baseline), 20 minutes after the treatments were applied (treatment), and 20 minutes after the treatments were removed (post treatment).

Results: Following the 20-minute treatment, tissue and skin temperatures for the ice with compression (7.4 ± 3.2 °C, 4.8 ± 3.0°C) respectively and slush bucket (8.5 ± 3.4 °C, 3.7 ± 2.1 °C) treatments were colder than the Game Ready® (18.6 ± 2.8 °C, 13.9 ± 3.4 °C) treatment (P<0.001), but did not differ from one another (p=0.48 and 0.49). Temperatures for all three modalities differed (p<0.001) both in the tissue and on the skin following the post treatment period, Game Ready® > ice with compression > slush bucket.

Conclusion: When looking at tissue temperature differences in young healthy subjects, after a 20-minute treatment at the sinus tarsi, Game Ready® on the medium setting and with a large sleeve did not cool as well as ice with compression or a slush bucket. Due to the poor fitting sleeve of the Game Ready® system, the results could have been affected, so caution must be taken when interpreting these results.

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Holwerda, S. W., Trowbridge, C. A., Womochel, K. S., & Keller, D. M. (2013). Effects of Cold modality application with static and intermittent pneumatic compression on tissue temperature and systemic cardiovascular responses. *Sports Health: A Multidisciplinary Approach*, *5*(1), 27–33. doi:10.1177/1941738112450863
Level of Evidence: Oxford 3b, PEDRO N/A

Purpose: To investigate the cardiovascular responses and tissue temperature decreases of common therapeutic applications of cryotherapy, including ice bag/elastic wrap and the continuous circulating water and intermittent pneumatic compression provided by the Game Ready® system.

Methods: Ten healthy subjects participated in four cryotherapy sessions (30-minute cryotherapy treatments with 30-minute passive recovery). Ice with elastic wrap and Game Ready® (GR) with no, medium (5-50 mmHg), and high compression (5-75 mmHg) were the treatment methods. Outcome measures included intramuscular (T_{IM}), skin surface (T_{SF}), and oral temperature (T_{ORAL}),as well as mean arterial pressure (MAP), heart rate (HR), rate pressure product (RPP), forearm blood flow (FBF), and forearm vascular conductance (FVC). An intramuscular-implantable tissue thermocouple was used to measure T_{IM} 1.5 cm below the subcutaneous adipose layer of the subject's left distal thigh and a Type-T copper constantan thermocouple measured T_{SF}.

Results: Peak intramuscular temperature changes from baseline were –14 ± 2°C (ice), –11 ± 6°C (GR_{HIGH}), –10 ± 5°C (GR_{MED}), and –7 ± 3°C (GR_{NO}). Ice cooled the muscle the most, while GR with medium and high compression cooled more than GR without compression ($P < 0.05$). Forearm blood flow and forearm vascular conductance decreased after baseline ($P < 0.05$), but there were no differences between treatments.

Conclusion: The application of cold and intermittent pneumatic compression using GR did not produce acute cardiovascular strain that exceeded the strain produced by standard ice bags/elastic wrap treatment. Therefore, the GR treatment is just as safe when comparing it to ice alone. Greater temperature decreases are achieved with medium- and high-pressure settings when using the GR system. However, ice had greater tissue cooling capacity than the GR on any setting.

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Kraeutler, M. J., Reynolds, K. A., Long, C., & McCarty, E. C. (2015). Compressive cryotherapy versus ice—a prospective, randomized study on postoperative pain in patients undergoing arthroscopic rotator cuff repair or subacromial decompression. *Journal of Shoulder and Elbow Surgery*, *24*(6), 854–859. doi:10.1016/j.jse.2015.02.004
Level of Evidence: Oxford 2a, PEDRO N/A

Purpose: To compare the effect of Compressive Cryotherapy (CC) versus Standard ice wrap (IW) on pain during the immediate postoperative week in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression.

Methods: Patients scheduled for rotator cuff repair or subacromial decompression were randomized into either CC or IW for post-operative week one. Patients were told to apply their respective cryotherapy for one hour followed by one hour of no treatment for the first 72 hours post- operatively (days 0-2) during all waking hours. For days three to seven, patients were instructed to apply cryotherapy two or three times per day, any time of day, for one hour each time. The CC patients were instructed to adjust the compression level according to their comfort and to set the temperature to the coldest temperature tolerated. All patients were also instructed to complete a ‘‘diary’’ each day, which included Visual Analog Scale scores with average daily pain and worst daily pain, total pain medication usage, as well as the number of times that cryotherapy was applied each day and the duration of each application. At the first postoperative appointment, each patient was asked to complete a modified version of the acute 12-Item Short Form Health Survey (SF-12).

Results: Average scores for the SF-12 physical subscore were 33.9 and 34.2 for the CC and IW groups, (P=.93). No significant differences were found in average pain, worst pain, or morphine equivalent dosage (MED) on days zero to seven. The CC group used a higher MED every day, although this difference was not statistically significant. The average total MED during postoperative days zero to seven was also higher in the CC group (201 vs. 154), but was not statistically significant (P=.28).

Conclusion: The results indicate that there is not a significant benefit to use of CC over standard IW in patients undergoing rotator cuff repair or subacromial decompression. It is unknown if CC devices are a cost-effective option for postoperative pain management in this population of patients. More research is

needed in this area.

Leegwater, N. C., Willems, J. H., Brohet, R., & Nolte, P. A. (2012). Cryocompression therapy after elective arthroplasty of the hip. *Hip International*, *22*(5), 527–533. doi:10.5301/HIP.2012.9761
Level of Evidence: Oxford 3a, PEDRO

Purpose: To study the effect of intermittent cryo-compression therapy on pain scores, analgesic use, and wound discharge. In addition, the feasibility of the system was assessed together with patient satisfaction following elective total hip arthroplasty.

Methods: Thirty patients undergoing elective hip arthroplasty for end-stage osteoarthritis were included. Patients were randomized into either the intervention group who received intermittent cryo-compression or a control group who received a compression bandage. Before and after treatment, numeric rating scale pain scores, ear temperature, blood pressure, heart rate, and use of medication for the intervention group were recorded. In the control group, patients' recordings were performed once. Hemoglobin, hematocrit and mean corpuscular volume were measured on day one and day three postoperatively. The dressing was inspected daily and discharge through was recorded (yes or no), and two days after surgery the wound was inspected. On the second postoperative day, total morphine usage through the patient controlled analgesia pump was recorded and then discontinued. All orally administered morphine at the patient's request was noted. At discharge, patients were asked to fill in a standardized questionnaire about their experience with the Game Ready System®. After discharge, all patients were evaluated at six weeks and again at one year postoperatively.

Results: The intervention group had a 0.55 mmol/L (p= 0.027) smaller decline in hemoglobin level on post-op day one. Total oramorph usage in the control group was 100 mg compared to 84.7 mg in the intervention group (p= 0.593). Lower discharge rates in the intervention group (p= 0.053). The mean total hospital stay in the intervention group was 4.75 days compared to 5.0 days in the control group (p= 0.633).

Conclusion: This study found a decrease in post-operative blood loss, a trend towards less wound discharge, and lower morphine usage in the cryocompression group. These findings could indicate decreased metabolic activity in the affected area, leading to a reduction in edema. However, this outcome

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measure was not assessed and can be cautiously inferred.

CDIC vs Ice and Compression Post TKA

Murgier, J., Cailliez, J., Wargny, M., Chiron, P., Cavaignac, E., & Laffosse, J. M. (2017). Cryotherapy with dynamic intermittent compression improves recovery from revision total knee arthroplasty. *The Journal of Arthroplasty*. doi:10.1016/j.arth.2017.03.052
Level of Evidence: Oxford 3b, PEDRO N/A

Purpose: To assess the efficacy of cryotherapy with dynamic intermittent compression (CDIC) in relieving post-op pain, decreasing blood loss, and improving functional scores after revision total knee arthroplasty (rTKA).

Methods: Forty-three subjects were enrolled at a single institution and divided into either a control group using a cold pack-regular cold application four hours per day using a cold pack or an experimental group with CDIC-two 8-hour cycles over a 24-hour period, 3 x 30 minute on:off cycles, with the temperature set at 8^{O}C. Both treatments were administered for 72 hours. Blood loss and Visual Analog Scale (VAS) scores were taken postoperative at day three, and function was assessed using the Oxford score at six months postoperatively.

Results: Following the intervention, the total blood loss was lower in the CDIC group than in the control group (260 vs 465 mL; $P < .05$). The transfusion rate was lower in the CDIC group (8% vs 42%; $P < .05$), and the mean lowest hemoglobin level was lower in the control group (8.5 g/dL (±1.2) vs 9.6 (±1.6); $P < .005$). Pain scores on the Visual Analog Scale at rest on day three were lower in the CDIC group than in the control group (1 vs 3; $P < .05$). The cumulative morphine intake at day five was not significantly different between groups. The Oxford functional score at six months postoperative was higher in the CDIC group than in the control group (42 vs 40).

Conclusion: The researchers concluded that patients using a CDIC following a rTKA had an improved recovery. Therefore, this type of device may be more effective than ice alone should be integrated into daily practice.

Murgier, J., & Cassard, X. (2014). Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study. *Orthopaedics & Traumatology: Surgery & Research*, *100*(3), 309–312. doi:10.1016/j.otsr.2013.12.019
Level of Evidence: Oxford 3b, PEDRO N/A

Purpose: To compare the efficacy of these two compression modalities combined with cryotherapy in relieving postoperative pain and restoring range of knee motion after ligament reconstruction surgery.

Methods: Thirty-nine consecutive patients who underwent primary anterior cruciate ligament (ACL) reconstruction were included in this prospective single-center study. Twenty subjects received cryotherapy combined with dynamic intermittent compression (CDIC) and 19 received cryotherapy and static permanent compression (CSPC). The use of the CDIC device consisted of 30 minutes on/30 minutes off at a low pressure, in the post-anesthesia care unit and until patient discharge (24 hours). The temperature was set at 0° C and could be adjusted based on patient tolerance. The use of the CSPC consisted of 30 minute sessions every two hours for five days total. The amounts of analgesic drugs used were recorded and the quality of the analgesia was assessed using a Visual Analog Scale (VAS) score at six hours after surgery, and at hospital discharge on the day after surgery. Range of knee motion was evaluated at hospital discharge by the same surgery-department physiotherapist.

Results: The mean VAS pain score was 2.4 in the CDIC group and 2.7 in the CSPC group ($P = 0.3$). Corresponding values were 1.85 vs. 3 ($P = 0.16$) at hour 6 and 0.6 vs. 1.14 ($P = 0.12$) at discharge. Mean range of knee flexion at hospital discharge was 90.5° (range, 80° –100°) in the CDIC group and 84.5° (range, 75° –90°) in the CSPC group ($P = 0.0015$). Tramadol consumption was significantly lower in the CDIC group: 57.5mg (range, 0–200) vs. 128.6 mg (range, 0–250) in the CSPC group ($P = 0.023$). None of the patients in the CDIC group required step 3 analgesics. In contrast, patients in the CSPC group had a mean morphine consumption of 1.14 mg (range, 0–8) ($P < 0.05$)

Conclusion: The authors concluded, based on the results, that CDIC treatment decreases analgesic drug requirements and improves the postoperative recovery of range of knee motion after ACL reconstruction. This indicates that a CDIC might be a better option than ice with static compression in reducing pain and improving ROM following ACL reconstruction.

Su, E. P., Perna, M., Boettner, F., Mayman, D. J., Gerlinger, T., Barsoum, W., Lee, G. (2012). A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. *Journal of Bone and Joint Surgery - British Volume*, *94–B*(11_Supple_A), 153–156. doi:10.1302/0301-620X.94B11.30832
Level of Evidence: Oxford 2b, PEDRO 4/10

Purpose: To evaluate if 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 versus ice and static compression after TKA surgery.

Methods: 280 patients enrolled at 11 international sites were randomized to treatment with a cryopneumatic device or ice with static compression. Both treatments were initiated within three hours post-operation and used at least four times per day for two weeks, 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 titrated for cooling and pressure by the patient to their comfort level. Outcomes regarding 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 Scale (VAS) score and narcotic consumption were measured post-operatively.

Results: There was significantly lower 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, in the treatment group ($p < 0.05$). Between two and six weeks, there was no difference in the total amount of narcotics consumed amongst 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 satisfaction, with greater satisfaction in the treatment group ($p < 0.0001$). There was no difference in ROM, TUG, VAS, or knee girth at six weeks.

Conclusion: The researchers concluded that patients who were treated with a cryopneumatic device after TKA consumed significantly less narcotics than patients who used ice and static compression. With a decrease in narcotic consumption they hypothesized that fewer side effects, such as constipation, nausea, light-headedness, would be seen. This study adds to the research regarding the efficacy of using a

cryopneumatic device, and gives objective results to the claims made by the device companies.

Waterman, B., Walker, J., Swaims, C., Shortt, M., Todd, M., Machen, S., & Owens, B. (2012). The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction. *Journal of Knee Surgery*, *25*(2), 155–160. doi:10.1055/s-0031-1299650
Level of Evidence: Oxford 3a, PEDRO N/A

Purpose: To evaluate and compare the effectiveness of cryotherapy with or without intermittent pneumatic compression after anterior cruciate ligament (ACL) reconstruction, focusing on postoperative edema, pain, and patient-reported outcome measures.

Methods: 36 patients undergoing ACL reconstruction were included in this prospective randomized controlled trial. They were randomized to cryotherapy/compression device or a standardized ice pack. Both groups were told to use of their type therapy for at least three sessions per day for 30 minutes duration and return to the clinic at one, two, and six weeks postoperatively. The same standard postoperative ACL rehabilitation protocol was used for both groups. Outcome measures used in this study were 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 were obtained as a measure of postoperative edema, and narcotic medication use was recorded by questionnaire.

Results: At six weeks postoperatively, 15 of 18 (83.3%) of all patients in the cryotherapy/compression device group had discontinued use of all pain medication, compared with 5 of 18 patients (27.8%) in the control group, ($p= 0.0008$). Circumferential knee measurements had no statistically significant differences between or within the two groups across any time intervals. Comparison of absolute VAS values between groups at all postoperative points had no statistically significant differences. However, mean differences in VAS relative to the preoperative measurement, the cryotherapy/compression device group had significantly better improvements in VAS than the control group at postoperative week two ($p=0.023$) and week six ($p < 0.0001$). No statistically significant differences in Subjective Patient Outcome Scores were detected between the control and the cryotherapy/compression device groups at all time intervals. Average SANE scores were higher in the cooling compression group at one, two, and six weeks

postoperatively when compared with the control group, but were not statistically significant.

Conclusion: The authors concluded the use of cryotherapy and compression in the post-operative period after ACL reconstruction results in improved short-term pain relief and a greater likelihood of independence from narcotic use compared with cryotherapy alone. This type of therapy is a reasonable treatment method when looking to reduce post-op pain.

Appendix B: Article Analyses

Hawkins, J., Shurtz, J., & Spears, C. (2012). Traditional cryotherapy treatments are more effective than game ready® on medium setting at decreasing sinus tarsi tissue temperatures in uninjured subjects. *Journal of Athletic Enhancement*, *1*(2). doi:10.4172/2324-9080.1000101

Level of Evidence: Oxford 3b **Pedro: N/A**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose was stated in the abstract and the introduction of the article. "The purpose of this study was to compare the cooling abilities of the CDIC device, ice with compression, and a slush bucket" (pg. 2).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the article the relationship between pain and cryotherapy. As well as the various cryotherapy options. The authors cited articles showing how ice and compression are more effective than ice alone. They also discussed the claims of the cryo-compressive device Game Ready®. They also briefly mentioned the gaps in the knowledge around this budding technology. In that no research has compared three different methods and their effectiveness on tissue cooling.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
	There are no internal validity concerns regarding with assignment, attrition, history, maturation, testing, or statistical regression. One potential threat to internal validity is the instrumentation.

➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	Due to the poor fitting sleeve of the cryo-compressive system, the tissue cooling capacity was not as effective as the slush bucket and ice bag. The poor fit could have lead to results that would not have been seen if the sleeve fit snug on the subject's ankles. Another threat involving instrumentation was the fact that there was no standardization for compression when wrapping the ice bag. The researchers practice wrapping the compression wrap at 35-40 mm-Hg, but during the actual testing there was no way of knowing if this pressure was applied. Having more or less pressure in the wrap could affect the results. The last threat to internal validity is that neither the researchers nor the subjects were blinded to the treatment. This may cause some bias of results.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
1. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	No, subjects were not randomly assigned to treatment order, all the subjects participated in the three different treatment sessions. There was no control or experimental group. Not having different groups for each treatment and assessment makes it impossible to randomize potentially effecting the validity of the research.
2. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, demographics on average age, height, and weight. The subjects were similar from what could be deduced for the mean and SDs given. There were 10 females and 10 males that participated in the intervention. The only other demographics given was a very broad statement that the subject were healthy and uninjured.

3. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, no blinding was possible since the subjects new to which modality was being used at each session. Since the researchers were looking at healthy subjects, all of the data was collected for each treatment within an hour, and there was no opinion associated outcome measures I don't think not blinding the subject affected the internal validity.
4. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	Yes, since all the subjects participated in each of the different trails, there were no assigned treatment groups. The order to which the subjects received the treatments was randomized, but it was evident what treatment the subject was receiving when they came in for each trial. Since all of the subject underwent the same trials I don't think there would be a risk to the internal validity. However, there is still the chance of biased results.
5. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the experimental procedures were the same for each subject.
6. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the investigators were measuring cooling potentials of three different cooling methods likely seen in a rehab facility. There was a 20-minute treatment session, which is very typical. as well as a 20 minute follow up to measure a re-warming period. This was a sufficient amount of time to look at how much the tissue was cooled down and how effective each method was at cooling.
7. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	Yes, all 20 subject completed the three treatment sessions.

8. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	There was no control/comparison group in this study therefore, an intention to treat analysis was not completed.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
9. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	The statistical findings are as followed Ice with compression and the Slush bucket differed from the Game Ready® (Sinus tarsi tissue: F= 56.4, *P*<0.001; Tukey<0.001) after the treatment and the post treatment re-warming periods, but not from each other (Tukey=0.85) Ice with compression and the slush bucket differed from the Game Ready® (Sinus tarsi skin F= 56.4, *P* 0.001; Tukey 0.001) after the treatment and the post treatment re-warming periods, but not from each other (Tukey=0.08) Based on the statistical findings The ice bag with compression and the slush bucket resulted in significantly greater cooling than the Game Ready® at both time points(treatment and post treatment), but did not differ from one another. This means that the CDIC device was not as effective at cooling the tissues as the other two methods. This could potentially mean that when looking at tissue cooling alone at the ankle, basic ice with compression or a slush bucket can have have a better indication for use.
10. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	

11. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. Without this data it is hard to determine if these results are significant for the patients. I still will use this evidence, because the study was well performed and does give relevant information about the effectiveness each method has on tissue cooling.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
12. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	All of the interventions are possible in my clinic. Base on the result of this study the ice or slush bucket are more advantageous when it comes to tissue cooling and in general more cost effective than the cryo-compressive device. Since it is hard to bill for the modality of ice it would make more sense based on the findings in the article to use the cheaper ice or slush bucket when tissue cooling is the main goal.
13. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	No, the subjects were young, healthy, and uninjured. The intervention was also done on the ankle, and one of the interventions (the slush bucket) is not practical to use on a patient with a TKA. My patient is about 20 years older and has just underwent TKA surgery. I believe I can still use this information based on the methods used in the article. Even though the subjects were

	different from my patient and the area treated was not similar. This intervention can still be used if my patient could not tolerate direct ice contact.
14. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	There were no benefits seen in using the cryo-compressive device in this article. However, my patient does not have any of the contraindicated conditions for using a cryo-compressive, so the risk of using this device are very minimal. I would be comfortable only using ice if my patient's insurance did not cover this type of device. I don't think there would be any risks or detriments to healing if only ice and compression was used. Especially since this article found that ice was actually better at cooling than a cryo-compressive device.
15. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes, based on the results of the study, my patient would like to have adequate and effective tissue cooling using cryotherapy. However, this article only looked at tissue cooling. There were no outcomes for edema or pain, both of which my patient is experiencing.
16. Are there any threats to external validity in this study?	Yes, the subjects were young and healthy and did not represent a population post TKA. Therefore, these results might not be repeatable with a different more varied population.

The bottom line from this study is that ice and compression or slush buckets were more effective at decreasing sinus tarsi tissue temperatures and sinus tarsi skin temperatures, compared to the cryo-compressive device. Leading to more effective cooling when using the first two types of cooling methods.

Holwerda, S. W., Trowbridge, C. A., Womochel, K. S., & Keller, D. M. (2013). Effects of Cold modality application with static and intermittent pneumatic compression on tissue temperature and systemic cardiovascular responses. *Sports Health: A Multidisciplinary Approach*, *5*(1), 27–33. doi:10.1177/1941738112450863

Level of Evidence: Oxford 3b **Pedro: N/A**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose was clearly stated in the articles introduction. "The purpose of this study was to investigate the cardiovascular responses and tissue temperature decreases of common therapeutic applications of cryotherapy, including ice bag/elastic wrap and the continuous circulating water and intermittent pneumatic compression provided by the Game Ready system®" (pg. 28).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the authors provided relevant background and gave a thorough literature review of information regarding the purpose of their study. The authors mentioned researched benefits in utilizing cryotherapy. They also gave a full explanation of how the Game Ready System® (GRS) works and the contraindications to using a GRS. They acknowledged gaps in the research and knowledge regarding arterial blood pressure and other cardiovascular responses to the application of therapeutic cooling (≥ 30 minutes) and compression. As well as whether the therapeutic combination of cold and different levels of intermittent pneumatic compression will elicit further increases in cardiovascular strain.

	The need for this research is for a better understanding of the cardiovascular and systemic response to cooling when using ice and compression compared to a GRS. It also investigates whether or not the GRS provides adequate tissue cooling.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	There are no internal validity concerns regarding assignment, attrition, history, testing, instrumentation, or maturation. One possible threat to the internal validity of the research is that the researchers nor the subject were blinded to the trials this may cause some bias of results.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
17. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	No, subjects were not randomly assigned to treatment order, all the subjects participated in the four treatment sessions. There was no control or experimental group. Not having different groups for each treatment and assessment makes it impossible to randomize potentially effecting the validity of the research.
18. Were the groups similar at the start of the trial? Did they report the demographics of the study groups?	Yes, demographics on average age, height, weight, and thigh skinfold mean was reported. The subjects were similar from what could be

a. **If they were not similar – what differences existed?**	deduced for the mean and SDs given. The major difference in the subjects was the inequality of women to men there was 1 woman and 9 men who participated.
19. **Did the subjects know to which treatment group they were assign?** a. **If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, no blinding was possible since the subjects new to which modality was being used at each session. Since the researchers were looking at healthy subjects, all of the data was collected for each treatment within an hour, and there was no opinion associated outcome measures I don't think not blinding the subject affected the internal validity.
20. **Did the investigators know who was being assigned to which group prior to the allocation?** a. **If they were not blind, what are the potential consequences of this knowledge for the study's results?**	Yes, since all the subjects participated in each of the different trails, there were no assigned treatment groups. The order to which the subjects received the treatments was randomized, but it was evident what treatment the subject was receiving when they came in for each trial. Since all of the subject underwent the same trials I don't think there would be a risk to the internal validity. However, there is still the chance of biased results.
21. **Were the groups managed equally, apart from the actual experimental treatment?** a. **If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the experimental procedures were the same for each subject.
22. **Was the subject follow-up time sufficiently long to answer the question(s) posed by the research?** a. **If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the investigators were looking at the systemic and cardiovascular response as well as the cooling effects of ice and compression versus the GRS. A 30-minute treatment time is pretty standard for cryotherapy and the effects of the treatment can be seen well with in that time frame. There was also a 30-minute passive recovery time which again is sufficient for the body to respond and recover once the modality has been removed.

23. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	Yes, all 10 subjects completed the 4 therapeutic treatments.
24. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	No, only 7 subjects' data were collected for the forearm blood flow (FBF) and forearm vascular conductance (FVC) data. There was no control/comparison group in this study so an intention to treat analysis was not completed.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
25. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	The statistical findings are as followed The 95% confidence intervals for average temperature treatment were 0.46–0.51°C (ice bags), 0.6–1°C ($CDIC_{NO}$), 0.8–1.4°C ($CDIC_{MED}$), 0.6–1.1°C ($CDIC_{HIGH}$). $CDIC_{NO}$ produced significantly less muscle cooling than ice bags, $CDIC_{MED}$, and $CDIC_{HIGH}$ from 10 to 40 minutes ($P < 0.05$). Ice bags provided greater muscle cooling from time points 10 to 45 minutes when compared to $CDIC_{MED}$ and $CDIC_{HIGH}$ ($P < 0.05$). Ice bags provided greater muscle cooling than $CDIC_{MED}$ at time points 50 and 55 minutes ($P <$

	0.05). Ice bags provided greater muscle cooling than $CDIC_{NO}$ at 5 minutes and 45 to 60 minutes ($P < 0.05$). Ice bags had greater intramuscular peak change than $CDIC_{NO}$ ($p < 0.001$, d = 1.3). Ice bags had a greater skin peak change than all CDIC conditions ($p < 0.001$, d > 0.88). $CDIC_{HIGH}$ had a greater skin peak change than $CDIC_{NO}$ ($p < 0.001$, Cohen d = 0.41). Forearm blood flow at baseline was greater than all other time points ($P = 0.008$, $1 - \beta = 0.87$, $\eta^2 = 0.77$). Forearm vascular conductance at baseline was greater than all other time points ($P = 0.006$, $1 - \beta = 0.89$, $\eta^2 = 0.98$). Mean arterial pressure at 0.5, 1.5, and 5 minutes was greater than baseline ($P = 0.004$, $1 - \beta = 0.93$, $\eta^2 = 0.71$). Rate pressure product at 0.5, 1.5, and 5 minutes was greater than baseline ($P < 0.001$, $1 - \beta = 0.99$, $\eta^2 = 0.98$). Heart rate at 5 minutes was greater than during passive recovery ($P < 0.001$, $1 - \beta = 0.71$, $\eta^2 = 0.35$).
26. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	These statistical findings indicate that ice and compression have greater tissue cooling than any of the CDIC settings. However, $CDIC_{HIGH}$ or $CDIC_{MED}$ appear to be adequate to achieve intramuscular cooling to ~25°C. These results indicate adequate production of moderate to complete skin analgesia. As for the cardiovascular and systemic response, while there were increases in HR, MAP, and RPP during the early stages of

	tissue cooling, they did not exceed typical elevations reported during exercise or experimental cold exposure. Indicating that both ice and compression and the CDIC are safe for healthy individuals
27. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	The only clinically meaningful results were the reductions in skin temperature (12°C to 17°C) that were achieved within 5 minutes using ice(95% CI -17.9, –8.9) and within 10 to 15 minutes using CDIC with or without compression(CI 95% $CDIC_{NO}$ –8.5, –4.8, $CDIC_{MED}$ –12.9, –6., and $CDIC_{HIGH}$ –14.5, –6.7). As well as the statistically significant p-values reported above. These finding indicate the efficacy of using ice or GRS as part of a treatment strategy. I will use this evidence, because the study was well performed and does give relevant information about the GRS.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
28. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	No, while there was a decrease in skin surface temperature and intramuscular temperature regardless of method of cooling. Ice was more effective at cooling compared to CDIC. Ice is also a lot more readily available, easily applied, and affordable compared to the CDIC. Ice would be a better option for tissue cooling especially if my patient's insurance did not cove the CDIC. However, if ice is not tolerated well by my patient a CDIC would be a sufficient alternative.
29. Are the study subjects similar to your patient/ client?	No, the subjects were young, healthy, and uninjured. My patient is about 20 years older and

a. If not, how different? Can you use this intervention in spite of the differences?	has just underwent TKA surgery. However, I believe I can still use this information based on the treatment method and the application site. While the subjects are not similar the treatment would be, therefore, I could still use this intervention.
30. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, and as the article results indicate the cardiovascular effects did not exceed typical elevations reported during exercise or experimental cold exposure. So the risk of using this device are very minimal. According to the results there would be no detriment to using either cryotherapy modality as adequate cooling was achieved by each. However, if my patient's insurance did not cover this type of device I don't think there would be any risks or detriments to healing if only ice and compression was used.
31. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	Yes, based on the results of the study, my patient would like to have adequate and effective tissue cooling using cryotherapy and she would like to limit any adverse risks when using a cryotherapy. Both of which were seen in this article regardless of type of cryotherapy method However, caution in interpreting and utilizing these results will be taken due to the patient population, small sample size, and effectiveness of the CDIC device. Cost and convince also need to be considered, as well as the level of evidence in the article. With that in mind, basic ice and compression is more cost effective and are likely to have similar outcomes.

32. Are there any threats to external validity in this study?	Yes, the subjects were young and healthy and did not represent a population post TKA. Therefore, these results might not be repeatable with a different more varied population.

The bottom line from this study is that adequate intramuscular cooling and clinically meaningful reductions in skin temperature were attained using ice using Game Ready® system with or without compression. The cardiovascular response to a 30-minute cold treatment with added static or intermittent pneumatic compression appears relatively safe in otherwise healthy individuals.

Kraeutler, M. J., Reynolds, K. A., Long, C., & McCarty, E. C. (2015). Compressive cryotherapy versus ice—a prospective, randomized study on postoperative pain in patients undergoing arthroscopic rotator cuff repair or subacromial decompression. *Journal of Shoulder and Elbow Surgery*, *24*(6), 854–859. doi:10.1016/j.jse.2015.02.004

Level of Evidence: Oxford 2a Pedro: N/A

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose is clearly stated in the article's abstract and in the introduction. "The purpose of this study was to compare the effect of CC vs. ice on pain during the immediate postoperative week in patients undergoing shoulder arthroscopy for rotator cuff repair or subacromial decompression" (pg. 855).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, there is relevant information about the research topic provided in the article. The article references benefits of both cryotherapy and compression in the early post-op period for patient undergoing rotator cuff repair. The article identifies that there has not been an investigation into comparing continuous compression with cryotherapy and ice alone in the current research.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***

➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	There are a few threats to internal validity in this study. Attrition of patients is the first possible threat. Eleven patients were excluded for failing to fill out pain diaries or non-adherence to research protocol. Their data was thrown out and no intention to treat analysis was done. Different surgical procedures were done based on injury. Therefore, the outcomes are different for each patient based on the surgery preformed and the technique used. However, patients were stratified on the basis of procedures performed, decreasing the risk for internal validity threats. Patients were not observed during treatment. There was no control over correct application or additional therapy done. Another potential threat was the inability to blind participants as to what group they were participating in making compensatory rivalry possible

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
33. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the patients were randomly assigned to either the treatment or control group using the random number generator function in Microsoft Excel.
34. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	No, the demographics were not reported in the article. making it impossible to identify similarities and differences in general demographics between groups. the average age was reported in each group and it was similar. The surgical procedures were reported and were similar between groups with the exception of subacromial decompression and distal clavicle excision being higher in the treatment group.
35. Did the subjects know to which treatment group they were assign?	Yes, no blinding can exist as patients notice the use and are able to control the settings of the cold

a. If yes, what are the potential consequences of the subjects' knowledge for this study's results	compression therapy. This could lead to compensatory rivalry which might affect the internal validity.
36. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No due to the randomization the investigators did not know who was being assigned to which group.
37. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	No, there was no mention of managing the groups equally pre-op, during surgery, or post-op. It can be inferred that there was no set standard of treatment between subjects. Not having a procedure for patient management post-op can affect recovery and the results. It can also have a big impact on the external validity.
38. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the researchers were looking to see if CC would affect pain during the immediate post-op week. However, this surgery requires months of recovery. Only looking at a short time frame might not give enough information on the big picture of rotator cuff surgery recovery.
39. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	No, eleven patients were excluded. The authors did not analyze their data for the results of the study.
40. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	No, the data from the excluded subjects was not analyzed. If the data was included there might have been potential for statistical significance in the results.

Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
41. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **42. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	Average scores for the SF-12 physical subscore were 33.9 and 34.2 for the CC and IW groups, respectively (P 1⁄4 .93). Average scores for the SF-12 mental subscore were 45.8 and 51.7 for the CC and IW groups, respectively (P 1⁄4 .10). No significant differences were noted regarding pain on the day or night of surgery. In addition, no significant differences were found in average pain, worst pain, or MED on days 0 to 7. The CC group used a higher MED every day, although this difference was not statistically significant on any single day. The average total MED during postoperative days 0 to 7 was also higher in the CC group (201 vs. 154), although this was not statistically significant (P 1⁄4 .28). Among patients who underwent rotator cuff repair (with or without subacromial decompression), no significant differences were found in terms of average pain, worst pain, or MED on any postoperative day between the CC and IW groups. Likewise, no significant differences were found in these variables among patients who underwent subacromial decompression (with or without rotator cuff repair). This study doesn't necessarily reflect my patient since they underwent a completely different operation, but it is still relevant information to give the patient and to use for clinical practice in general. These results indicate that there is not any significant difference in pain reduction between cold compression and ice alone. The mechanism of injury is different but the general response process is the same for tissue, so this information is relevant in deciding the efficacy of a cold compression device.
43. Do these findings exceed a minimally important difference?	There are no reported minimally important differences for the outcome measures analyzed in

a. **If not, will you still use this evidence?**	this study, besides the statistically significant p-values reported above. Without this data it is hard to determine if these results are significant for the patients. I still will use this evidence, because it is conflicting evidence against the efficacy of a cold compression device. With this research and these results, it can be argued that ice alone is sufficient enough in supplying analgesic effects. However, there are a lot of internal and external validity issues as well as the fact that the surgical procedures are not in line with my patient's surgery. For those reasons this research will be used with caution.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
44. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Yes, this intervention is still appropriate for use. Using this device won't inhibit their recovery. However, it might not enhance it. With its higher cost and more cumbersome application it might not be the best option for the patient.
45. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	No, the study does not have similar subjects. The rotator cuff repair surgery preformed was different than my patient's TKA surgery, the location was different, and the general treatment protocol post-op are very different between the two types of surgery. However, the average age is similar to my patient and general tissue response is relatively the same regardless of surgical location. For these reasons this research can still be used in spite of the differences.
46. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, so the risk of using this device are very minimal. However, according to this study there are no real potential benefits from using the device ice had the same affects as the cold

	compression. If my patient's insurance did not cover this type of device, I don't think there would be any risks or detriments to healing if ice alone was used.
47. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	No, based on the results of this study this intervention does not fit within my patient's stated values. Paying more for a device did no decrease pain levels any better than ice does not seem cost effective or useful. However, the treatment site and surgery were different than my patient. Caution will be taken in utilizing the result and treatment for my own patient's situation and PT treatment.
48. Are there any threats to external validity in this study?	Yes, there was no standardized care post-op. the patients were instructed on the amount of time to use each treatment method, but compression and temperature were set to patient tolerance. This can lead to a lot of variability.

The bottom line from this article is that there is no statistically significant difference in pain reduction following rotator cuff repair surgery between cold compression therapy and a control group. There was a statistically significant increase in the use of narcotics from day 5-7 in the cold compression group. Cold compression devices have no effect on pain control compared to ice alone.

Leegwater, N. C., Willems, J. H., Brohet, R., & Nolte, P. A. (2012). Cryocompression therapy after elective arthroplasty of the hip. *Hip International*, *22*(5), 527–533. doi:10.5301/HIP.2012.9761

Level of Evidence: Oxford 3a **Pedro: N/A**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose is stated in the article's introduction. "To study the effect of intermittent cryo-compression therapy on pain scores, analgesic use, and wound discharge. In addition, the feasibility of the system was assessed together with patient satisfaction following elective THA" (pg. 2).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	The study gives relevant statics on total hip arthroplasty (THA), as well as possible benefits from previous research using cryotherapy and intermittent pneumatic compression. The researchers also state that No randomized controlled trial has been performed on the effects of combined cyclic compression and cryotherapy in total hip arthroplasty. With all of the hype over and claims on the benefits of using the intermittent cryo-pneumatic devices and the lack of evidence out there on their efficacy after surgery. This study helps to put evidence to the claims

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
	There are no internal validity issues regarding assignment, history, instrumentation, maturation,

➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	testing, or statistical regression. One potential threat is the attrition 4 subject did not receive the complete treatment, the could affect the results due to the fact that there was a small sample size. Another internal validity threat is compensatory rivalry. Since the subjects could not be blinded, the control group could have felt they were getting good enough treatment. one subject from the control group wanted to be allocated to the Game Ready System® (GRS) group. The treatment group could have also felt better because they knew were getting a specialized treatment thus potentially biasing the results. One other threat could have come from the changed in staff from day to day analyzing the wound discharge. They were not blinded and the analysis could have been inconsistent form day to day leading to observer bias.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
49. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, Randomization took place on the day of operation prior to surgery with the use of sealed opaque envelopes.
50. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, the study reported its demographics in a table. Yes, for the most part the groups were similar. The only major difference was the male to female ratio in the control group there were 4 males and 11 females. As opposed to the intervention group who had 8/7 male to female ratio.

51. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, no blinding can exist as patients notice the use and are able to control the settings of the GRS. This could lead to compensatory rivalry which might affect the internal validity.
52. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No due to the randomization the investigators did not know who was being assigned to which group.
53. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, all patients were managed equally pre-op, during surgery and post-op. They all had the same tests and measures done pre-op. The method of surgery, materials, and wound closure was the same for every subject. All subjects had the same pain medications, and the administration of the medication was managed equally.
54. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the investigators wanted to look at the the effects of the GRS on pain, analgesic use, wound discharge, feasibility of the system, and patient satisfaction. The subjects were assessed for 4 days post-op, 6 weeks, and a gain 1-year post-op. However, there was no information on outcome measures and results provided for the 1 year follow up. While there follow up time was sufficient to answer the posed questions I don't think their treatment time was long enough to assess pain. THA has a long recover period and I think the subjects and the study would have benefited from a longer treatment period.
55. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	No, 4 subjects did not complete the treatment. 1 patient in the control group wanted to be allocated to the GRS group, 2 patients in the intervention group had excessive perioperative blood loss, which necessitated exclusion and 1 patient in the intervention group GRS use was discontinued because of discomfort due to inability to urinate. The authors reported no differences between the two groups regarding baseline characteristics. No difference in regard to perioperative blood loss

	was found. However, there was no report on an intention to treat analysis. If the attrition wasn't handled properly, the internal validity could have been impacted negatively.
56. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	No, the investigators did not mention n intention to treat analysis for the allocated subjects. Since the sample size was small to begin with this attrition rate could have affected the results.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
57. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	When compared at POD 1, study group patients had a 0.55 mmol/L (p= 0.027) smaller decline in hemoglobin level. At POD 3 this advantage in hemoglobin levels persisted (0.47 mmol/L smaller decline in study group patients) Total oramorph usage in the control group was 100 mg compared to 84.7 mg in the intervention group (p=0.593) Lower discharge rates in the intervention group (p=0.349) The mean total hospital stay in the intervention group was 4,75 compared to 5,0 in the control group (p=0.633) The questionnaires on the Game Ready® experience were generally positive about cryo-compression treatment. Subjects reported their pain experienced was less.

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58. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	These statistical findings while minimal, still relevant information to give the patient and to use for clinical practice in general. These results indicate that there is a decrease in in blood loss which can indicate less peripheral leakage of blood and edema fluid. There was also a trend toward lower morphine usage. However, it was not statistically significant. The subjects also had an overall positive experience using the GRS. While the mechanism of injury is different the general response process is the same for tissue, so this information is relevant in deciding the efficacy of a cold compression device.
59. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. Without this data it is hard to determine if these results are significant for the patients. I still will use this evidence, because the study gives relevant information about the CDIC and its efficacy compared to other icing methods. This evidence will help to make an informed decision on the value of a CDIC device in a clinical setting.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	

Appraisal Criterion	*Reader's Comments*
60. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Yes, while this intervention was done in an acute care setting and with THA. The treatment is still feasible. The decreased blood loss, a trend toward decreased pain medication usage, and an overall positive patient experience using the CDIC. Is appealing to patients and therapists to help enhance recovery. However, the expense of the machine and the small, short term effects seen in this study might not be economically manageable.
61. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	No, the study does not have similar subjects. The THA surgery preformed was different than my patient's TKA surgery, the location was different, but the general treatment protocol post-op between the two types of surgery have some similarities. However, the general tissue response is relatively the same regardless of surgical location and surgery performed. For these reasons this research can still be used in spite of the differences.
62. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, even though there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, so the risk of using this device are very minimal. However, if my patient's insurance did not cover this type of device I don't think there would be any risks or detriments to healing if a basic ice and compression treatment was done.
63. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	The intervention does fit within my patients values of decreased pain levels, less pain medication consumption, and more comfort. All of which have been seen using a CDIC device in this article. However, caution in interpreting and utilizing these results will be taken due to, the different surgery, the variability of recovery from this surgery compared to recovery from TKA, and the risk to validity. Cost and convince also need to be considered, as well as the level of evidence

	in the article. With that in mind, basic ice and compression is more cost effective and are likely to have similar outcomes.
64. Are there any threats to external validity in this study?	Yes, since this was a completely different operation than what my patient had the results might not translate the same.

The bottom line of this study is patients using the GRS after THA are more likely to have a decrease in blood loss, a trend toward lower morphine use, and a generally positive experience using the device compared to those who just received compression bandages.

Murgier, J., Cailliez, J., Wargny, M., Chiron, P., Cavaignac, E., & Laffosse, J. M. (2017). Cryotherapy with dynamic intermittent compression improves recovery from revision total knee arthroplasty. *The Journal of Arthroplasty*. doi:10.1016/j.arth.2017.03.052
Level of Evidence: Oxford 3b Pedro: N/A

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose is stated in both the article's abstract as well as in the introduction. "The goal of this study was to assess the efficacy of cryotherapy with dynamic intermittent compression(CDIC) in relieving post-op pain, decreasing blood loss, and improving functional scores after revision total knee arthroplasty (rTKA)" (pg. 1).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	The researchers provided relevant background on the negative affects of rTKAs including, pain, decreased ROM, blood loss leading to systemic complications. As well as the roll cryotherapy can play in helping to mitigate some of these effects. They cited research using CDIC devices for ACL reconstruction and and primary TKA and its potential benefits. And brought to light gaps in studies regarding the use and potential benefits of CDIC devices in patients undergoing rTKA.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
	There are no internal validity threats regarding, assignment, history, attrition, maturation, instrumentation, or testing. There could be a

➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	threat to validity with compensatory rivalry since the participants would know whether or not they were in the control or test group. There could also be a bias due to the use of advanced anesthesia procedures, which could have caused a type II error.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
65. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	No, there was no report of the authors randomly assigning subjects to treatment groups. the population was divided into two groups. the patients in the control group were included between January 2013 and April 2014. The patients in the CDIC group were included between May 2014 and January 2015. Without randomization the researchers could have picked participants with a little more selectivity.
66. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	The groups were similar in age, BMI, gender, surgery time, tourniquet time, IT osteotomy, and patella resurfacing. There were more participants in the CDIC group 24 as opposed to 19 in the control group.

67. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the subject could not be blind to the groups they were in due to the experiment. The patient either used a device or did not. This could lead to compensatory rivalry which might affect the internal validity.
68. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	There was potential that the investigators knew who was being assigned to each group prior to allocation. The study did not mention randomly assigning groups. therefore, a potential consequence is the researchers could have selected specific patients for each group.
69. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, all of the participants received the same procedure using the same knee instrumentation, anesthesia protocol and anticoagulant therapy.
70. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the subjects were followed at 6-month post-op to complete the Oxford functional score questionnaire. This is sufficient time to answer the functional questions posed by the researchers. However, pain and blood loss were only assessed until 5 days post-op. There is a lot of recovery after a rTKA, for that reason treatment time and two of the three outcome measures were not assessed for nearly long enough. These results could potentially be different if the follow-up time was longer.
71. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	There was no report of any loss in participants. Therefore, nothing was done about attrition.
72. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?**	Yes, all of the subjects were analyzed in the groups they were randomized.

b. If the data were excluded, what are the potential consequences for this study's results?	
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
73. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI** **74. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?**	The statistical findings showed Pain at rest on day 3 was lower in the CDIC group than in the control group (1 vs 3; P < .05). The cumulative morphine intake at day 5 was not significantly different between groups The total blood loss was lower in the CDIC group than in the control group (260 vs 465 mL; P < .05). The hemoglobin and hematocrit levels were similar between groups. The transfusion rate was lower in the CDIC group (8% vs 42%; P < .05), and the mean lowest hemoglobin level was lower in the control group with 8.5 g/dL (±1.2) vs 9.6 (±1.6); P < .005. The Oxford score at 6 months postoperative was higher in the CDIC group than in the control group (42 vs 40). However, this was not statistically significant. No effect size or CI were included in this study While there was a reduction of pain on day three when the participants were using the devices and no difference in cumulative morphine at day 5 one could infer that the devices were helping to reduce the pain. It was also reported that narcotic use was reduced by -20 mg in the CDIC group. This reduction in pain and narcotics is appealing to patients. Total blood loss was also lower in the CDIC group indication less metabolic activity in the damaged tissues. There was also a trend toward higher functional scores at 6 months' post-op in the CDIC group. These results demonstrate the potential benefits of using a CDIC, especially in patients who experience more pain and discomfort after surgery. However, the benefits are only minimal and the longevity of these

	positive results is unknown do to the short treatment time of 3 days. More research needs to be done on the lasting effects of CDIC and a longer treatment time using the CDIC is needed in order to have convincing evidence that these devices show strong effectiveness over ice alone.
75. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. I will use this evidence because any decrease in pain, reduced narcotic consumption, lower blood loss, and improvements in function are very meaningful and powerful to patients especially those struggling in rehab.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
76. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Based on the researchers results there is some efficacy in using a CDIC device to reducing pain. However, the lack of treatment time and minimal follow up outcome measures, the lack of randomization and blinding does not convince me that this method is significantly better than ice alone. There is a slightly significant cost attached to the device for that reason more research needs to be done before it is used in my clinic.
77. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	Yes, based on the general demographics the participants are similar to my patient. However, my patient had a TKA so the surgery performed on these subjects was slightly different and less invasive than my patient's TKA. There is use to

	the research regardless in the differences in subjects from my patient. Using this data, I will be able to make a more informed decision on the efficacy of using this type of device on my patient.
78. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, even though there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, so the risk of using this device is very minimal. The researchers found some positive benefits or no difference between the two groups. With the benefits of decreased pain and decreased narcotic consumption seen this intervention could make the patient more comfortable during recovery without causing additional risks.
79. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	No, while the result indicated a decrease in blood loss and narcotic consumption in the CDIC group. The lack of blinding and randomization as well as potential for biased results gives some pause in regard to how effective CDIC devices are compared to basic ice and compression. Cost and convince also need to be considered, as well as the level of evidence in the article. With that in mind, basic ice and compression is more cost effective and are likely to have similar outcomes.
80. Are there any threats to external validity in this study?	Yes, there was no standardization of treatment after the 3 day of intervention. The procedure was done at a highly specialized TKA surgery; this specialty care may not be reproduced to the general public.

The bottom line from this study is that a CDIC reduced pain blood loss at three days' pot-op rTKA. A decreases in narcotic consumption for the treatment group was also reported, but it was not statically significant. There is potential for use of the CDIC device in an acute care setting to help enhance recovery of patients.

Murgier, J., & Cassard, X. (2014). Cryotherapy with dynamic intermittent compression for analgesia after anterior cruciate ligament reconstruction. Preliminary study. *Orthopaedics & Traumatology: Surgery & Research*, *100*(3), 309–312. doi:10.1016/j.otsr.2013.12.019

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Level of Evidence: Oxford 3b **Pedro: N/A**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose was stated in the abstract and discussion "Our objective was to compare the efficacy of these two compression modalities combined with cryotherapy in relieving postoperative pain and restoring range of knee motion after ligament reconstruction surgery" (pg. 309).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, the article presented information on the benefits of controlling post-op pain and the role non-pharmaceutical treatments can have on reducing inflammation and pain. They also cited research that looked at the affects of dynamic intermittent compression on tissue. The authors justified the need for this study by finding no previous study that has evaluated the efficacy of cryotherapy combined with dynamic intermittent compression (CDIC) in controlling post-op pain after knee ligament reconstruction. With all of the hype over and claims on the benefits of using the intermittent cryo-pneumatic devices and the lack of evidence out there on their efficacy after surgery. This study helps to put evidence to the claims

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	There are no concerns regarding internal validity with attrition, history, instrumentation, maturation, or testing. One threat to internal validity is the assignment method. There was no mention of randomization of participant to groups. Another potential threat was the inability to blind participants as to what group they were participating in making compensatory rivalry possible. However, the treatment time was so short (5 days post-op) and outcome measures were only collected until 1-day post-op. I do not think compensatory rivalry would have a major impact on internal validity. The sample size is fairly small in this study (39) so detection of statistical significance in VAS scores and narcotic consumption difficult.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
81. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	The authors did not mention randomizing the participants into the groups. Without randomization the investigators could have have selected only patients with characteristics that would potentially have favorable results following surgery. This can have a significant impact on internal validity
82. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	The two groups showed no significant differences for age, gender distribution, body mass index, or operative time. Yes, demographics were reported in this study.

83. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the subject could not be blind to the groups they were in due to the experiment. The patient either used a device or did not. This could lead to compensatory rivalry which might affect the internal validity.
84. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	Yes, without random group assignments it can be inferred that the investigators know who was being assigned to which group. Knowing which subject are in each group could lead the investigators to give more favor to the treatment group. There was also no report of the physical therapist taking ROM measurements being blinded to the groups. However, the treatment time was so short this knowledge would not have had a huge impact, but here is a chance for data and results to be skewed.
85. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the groups were managed equally. The same surgeon conducted the surgeries, all were managed with a short four-strand semi-tendinosus graft and the same screw. The analgesic drug use was standardized among participants and rehabilitation was also standardized to all participants.
86. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, based on the researcher's question the follow-up time was sufficient to answer their question. It was 1 day follow up so there could have been different results if follow and treatment time were longer.
87. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	Yes, all of the subjects that were enrolled completed the study.
88. Were all patients analyzed in the groups to which they were randomized	Yes, all of the subjects were analyzed in the groups they were randomized into.

Comment [TE3]: just FYI, abbreviations are fine in this section because it is your notes to yourself (ie this part would not actually get published)

(i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
89. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	The statistical findings from the study showed Cumulative mean paracetamol dose per patient was 3.8 g (range, 2–8) in the CDIC group and 4.29 g (range, 3–5) in the CSPC group (P = 0.19); corresponding values for ketoprofen were 235 mg (range, 100–400) and 228 mg (range 100–00) (P = 0.4). Tramadol consumption was significantly lower in the CDIC group: 57.5mg (range, 0–200) vs. 128.6 mg (range, 0–250) in the CSPC group (P = 0.023). None of the patients in the CDIC group required step 3 analgesics. In contrast, patients in the CSPC group had a mean morphine consumption of 1.14 mg (range, 0–8) (P < 0.05) The mean VAS pain score was 2.4 in the CDIC group and 2.7 in the CSPC group (P = 0.3). Corresponding values were 1.85 vs. 3 (P = 0.16) at H6 and 0.6 vs. 1.14 (P = 0.12) at discharge None of the patients in the CDIC group required step 3 analgesics. In contrast, patients in the CSPC group had a mean morphine consumption of 1.14 mg (range, 0–8) (P < 0.05) Mean range of knee flexion at hospital discharge was 90.5° (range, 80° –100°) in the CDIC group and 84.5° (range, 75° –90°) in the CSPC group (P = 0.0015). These findings indicate that in an acute setting, a statistically significant decrease in the consumption of some analgesic drugs and a statistically significant increase in knee flexion can be observed when using a CDIC device. It

90. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	was also reported that none of the CDIC treatment group required 3-step analgesics as opposed to the CSPC group in which there was a mean morphine consumption. This method of treatment is safe and can have more benefits than cryotherapy with static permanent compression. However, there was no long term follow up (1day post-op) and both treatments were only used for a reported 5 days post-op.
91. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. Without this data it is hard to determine if these results are significant for the patients. I still will use this evidence, there was a decrease in pain, reduced narcotic consumption, and increase ROM. While there are many factors that could potentially influence the results. This evidence will help in the clinical efficacy of a CDIC device compared to other methods.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
92. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	The intervention could be appropriate for use while this intervention was done in an acute care setting and my clinic is an outpatient clinic, this treatment is still feasible. However, the expense of the machine, the limited differences in results between groups, and its small, short term effects might not be the best option.
93. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	No, the study does not have similar subjects to my patient. They were all significantly younger and the mechanism of injury (ACL reconstruction) differs form my patient. I will still be able to use this information when determining the efficacy of this type of device for my clinic as

	well as the benefits that might be seen by my patient.
94. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, the potential short term benefits outweigh the potential risks in using this intervention. Some of the possible risks involved include a worsening pain, a decrease in ROM, contracture, reduced compliance, dependency on narcotics, and reduced prior level of function. Some benefits include decrease of pain and increase ROM. No adverse effects were seen in utilizing wither treatment method. Based on this study it is worth implementing this intervention if my patient is has a low tolerance for ice.
95. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	This intervention does fit my patient's values of, decreased pain levels and improved ROM. Both of which have been seen using a CDIC device from the article. However, caution in interpreting and utilizing these results will be taken due to the patient population, small sample size, lack of blinding, and potential for bias. Cost and convince also need to be considered, as well as the level of evidence in the article. With that in mind, basic ice and compression is more cost effective and are likely to have similar outcomes.
96. Are there any threats to external validity in this study?	Yes, there was potential for biased sample selection because it was not reported if the investigators, physical therapists, or post-op care unit was blinded to the groups. There is also a setting difference. The study took place in an inpatient acute care setting, whereas my patient is in out patient three weeks post-op.

The bottom line from this RCT is that in an inpatient acute care setting following ACL reconstruction, subjects using a CDIC device showed a reduction in narcotic consumption and no morphine consumption as well as in improvement in knee flexion ROM.

Su, E. P., Perna, M., Boettner, F., Mayman, D. J., Gerlinger, T., Barsoum, W., Lee, G. (2012). A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. *Journal of Bone and Joint Surgery - British Volume*, *94–B*(11_Supple_A), 153–156. doi:10.1302/0301-620X.94B11.30832

Level of Evidence: Oxford 2b **Pedro: 4/10**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	The purpose is clearly stated in the last paragraph of the introduction and briefly in the abstract "The Purpose of the study was to evaluate if 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." (pg.154)
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	This article discusses elements that can influence recovery from total knee arthroplasty(TKA). It gives sufficient background on the theory behind how compression reduces edema and intra-articular volume. It explains how cryotherapy affects pain and inflammation. The Authors provide information on previous studies that have also looked at clinical benefits of cryotherapy and compression versus ice with some stating there were benefits and other studies finding no difference. The Authors pointed out the small sample sizes, non-randomization, un-blinded, and short treatment times in the previous studies. There is no background on the prevalence of TKAs or its effect on function, return to work/normal living.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	There are a few concerns about internal validity in this study. There was no mention an attrition rate or an intention to treat. If there were drop-out from the program there is no way to tell if the data was modified to accommodate the losses, this could potentially affect the data. Since participants couldn't be blinded compensatory rivalry could also have impacted internal validity. History during the time of the study could have affected the validity. There are a lot of external factors that could have had an impact on recovery, that the researchers had no control of. There were less threats to internal validity for testing. The outcome measures used were standardized and an experienced blinded physical therapist conducted the tests. The only concern is multiple physical therapists were conducting the tests due to the use of 11 different sites.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
97. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the subjects were randomized into the test group or control group by the use of a blocked and stratified random number generator.
98. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	The demographics of the patients were not described in the study. Inclusion criteria consisted of being between the ages of 18-85 with a diagnosis of unilateral osteoarthritis. The only mention of demographics was that both groups were comparable with respect to gender, ethnicity, age, age and BMI. With very little demographic information, there is no way to tell

	how similar or different the groups were. Making it hard to account for confounding variables and recreating the patient population. Both of which affect the validity of the experiment.
99. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the subject could not be blind to the groups they were in due to the experiment the patient either used a device or did not.
100. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No, the investigators were blinded to which group each of the subjects were assigned.
101. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the subjects were randomized either the test or control group. According to the researchers the subjects were comparable in demographics. While there was no control over the operation or instrumentation used for the surgery, this makes it more realistic and generalizable to the greater population.
102. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, there was follow up at two and six weeks. By six weeks if the subject has not shown significant improvements in function, edema, and pain there might be an underlying issue. However, the subject only used the cryopneumatic device for two weeks. Healing is still going on well beyond two weeks, the results could have been much different if the participants used the devices longer.
103. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	There was no mention of an attrition rate, the only report from the researchers was compliance rates were similar between the two groups. internal validity and the the results of the outcome measures could have been impacted.
104. Were all patients analyzed in the groups to which they were	There was no report of an intention to treat analysis. With out this it is hard to determine if

randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	the results would have been the same with or without the lost subjects.
Are the valid results of this RCT important?	
Appraisal Criterion	***Reader's Comments***
105. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	Using SPSS version 12 as the statistical analysis system the results are as followed. No statistically significant difference in ROM, swelling, or functional testing between the two groups, Consumption of pain medication during the first 2 weeks, a statistically significantly lower amount of morphine equivalents used by the cryopneumatic group as compared with the ice and static compression group ($p < 0.05$). After discontinuation of the cooling and compression regimen, no difference in narcotic consumption between the two groups between two to six weeks was found. 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 ($p = 0.13$) Patient satisfaction was significantly higher in the cryopneumatic device group The significant difference in pain medication consumption at two weeks and overall patient satisfaction after using the cryopneumatic. This could have affected my patient's case. With a decrease in pain and a better an overall better experience working on ROM and functional activities could have been more comfortable and

106. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	more successful. However, with no affect on ROM, visual analog scale, TUG, and 6 min walk test at two and six weeks it is hard to justify the use of this device in clinic. I believe using this device for a longer period of time could have had more of a significant impact on results. For that reason I am I would use this device if my pt was not making the gain necessary due to pain and overall discomfort at PT.
107. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. I will still use the evidence, patient satisfaction and comfort along with decreased narcotic consumption is especially important with narcotic abuse becoming a growing problem.
Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
108. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	As stated above this intervention may be appropriate for those who are having a difficult time coping with pain; and discomfort using standard and compression and if the intervention time is longer than two weeks post-op.
109. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	There was not a good picture of the subject demographics reported by the authors, but in general yes. The subjects in this study were undergoing a TKA which is a significant population seen in clinic and had the same procedure as my patient.
110. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, even though there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac

	insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, so the risk of using this device is very minimal. The benefits in this study are fairly minimal. Getting pt buy in is very important and this device might help make their recovery more comfortable. Patients also consume less narcotics when using the cryopneumatic device, which can impact their overall health and well being.
111. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	No, while consuming less narcotics and being more satisfied, is very valuable. The lack blinding and potential for bias of results does give good evidence for the efficacy of utilizing CDIC device. Cost and convince also need to be considered, as well as the level of evidence in the article. With that in mind, basic ice and compression is more cost effective and are likely to have similar outcomes.
112. Are there any threats to external validity in this study?	Yes, there was no way to analyze the demographics. There was no report of exclusion criteria and minimal inclusion criteria. Without this information it could impact the reproducibility of the study. There was no set standard for compression using the cryopneumatic device after the participants were discharged.

The bottom line from this study is that there are few benefits to using a cryopneumatic device after a TKA. With significantly less narcotic consumption two weeks' post-op in the test group and an overall higher satisfaction rating in the test group, there is some efficacy in using a cryopneumatic device, especially for patient who do not tolerate ice well. However, with no difference between groups in ROM, VAS, TUG, 6 min walk, and girth at two and six weeks the cost per benefit is hard to rationalize

Waterman, B., Walker, J., Swaims, C., Shortt, M., Todd, M., Machen, S., & Owens, B. (2012). The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction. *Journal of Knee Surgery*, *25*(2), 155–160. doi:10.1055/s-0031-1299650

Level of Evidence: Oxford 3a **Pedro: N/A**

Is the purpose and background information sufficient?	
Appraisal Criterion	***Reader's Comments***
Study Purpose Stated clearly? Usually stated briefly in abstract and in greater detail in introduction. May be phrased as a question or hypothesis. A clear statement helps you determine if topic is important, relevant and of interest to you. Consider how the study can be applied to PT and/or your own situation. What is the purpose of this study?	Yes, the purpose is stated in the introduction and abstract. "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" (pg. 156).
Literature Relevant background presented? A review of the literature should provide background for the study by synthesizing relevant information such as previous research and gaps in current knowledge, along with the clinical importance of the topic. Describe the justification of the need for this study	Yes, there was relevant background provided by the Authors. The authors discussed and cited research on the benefits of cryotherapy and and the efficacy of using it for post-op patients. They also pointed out that there are few studies that have evaluated and compared how effective cryotherapy is with or without intermittent pneumatic compression after ACL reconstruction.

Does the research design have internal validity?	
Appraisal Criterion	***Reader's Comments***
	There are no concerns with internal validity regarding assignment, attrition, history, maturation, or testing. One threat to internal

➢ **Discuss possible threats to internal validity in the research design. Include:** ➢ **Assignment** ➢ **Attrition** ➢ **History** ➢ **Instrumentation** ➢ **Maturation** ➢ **Testing** ➢ **Compensatory Equalization of treatments** ➢ **Compensatory rivalry** ➢ **Statistical Regression**	validity is the inability to blind the participants to which group they were assigned. Knowing this information could potentially lead to compensatory rivalry. Another potential threat was the secondary patient outcome measures. They are not validated and could lead to inaccurate interpretation and results.

Are the results of this therapeutic trial valid?	
Appraisal Criterion	***Reader's Comments***
113. Did the investigators randomly assign subjects to treatment groups? **a. If no, describe what was done** **b. What are the potential consequences of this assignment process for the study's results?**	Yes, the subjects were randomly assigned using a random number generator with the even identification numbers being assigned to the CC treatment group and the odd identification numbers assigned to the control group.
114. Were the groups similar at the start of the trial? Did they report the demographics of the study groups? **a. If they were not similar – what differences existed?**	Yes, the subjects were similar at the start of the trial. There was no statistical significant difference between age, gender, height, weight, tourniquet time, and graft type. There was a difference in pre-op VAS scores with the treatment group having higher VAS scores. Yes, demographics were reported in this study.
115. Did the subjects know to which treatment group they were assign? **a. If yes, what are the potential consequences of the subjects' knowledge for this study's results**	Yes, the subject could not be blind to the groups they were in due to the experiment. The patient either used a device or did not. This could lead to compensatory rivalry which might affect the internal validity.

116. Did the investigators know who was being assigned to which group prior to the allocation? **a. If they were not blind, what are the potential consequences of this knowledge for the study's results?**	No due to the randomization the investigators did not know who was being assigned to which group.
117. Were the groups managed equally, apart from the actual experimental treatment? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, the groups had similar operations and graft types, as well as similar rehab protocols.
118. Was the subject follow-up time sufficiently long to answer the question(s) posed by the research? **a. If not, what are the potential consequences of this knowledge for the study's results?**	Yes, this study followed up at 1, 2 and 6 weeks' post-op, giving them sufficient time to answer the questions posed. However, ACL reconstruction rehabilitation takes well over that time frame. Having longer follow up visits could have produced more accurate results for the general population. Cryotherapy does have short term advantages so the treatment affects would not have been seen, especially if the experiment was discontinued at 6 weeks.
119. Did all the subjects originally enrolled complete the study? **a. If not how many subjects were lost?** **b. What, if anything, did the authors do about this attrition?** **c. What are the implications of the attrition and the way it was handled with respect to the study's findings?**	Yes, all the subject enrolled completed the study.
120. Were all patients analyzed in the groups to which they were randomized (i.e. was there an intention to treat analysis)? **a. If not, what did the authors do with the data from these subjects?** **b. If the data were excluded, what are the potential consequences for this study's results?**	Yes, all of the subjects were analyzed in the groups they were randomized into.
Are the valid results of this RCT important?	

Appraisal Criterion	*Reader's Comments*
121. What were the statistical findings of this study? **a. When appropriate use the calculation forms below to determine these values** **b. Include: tests of differences? With p-values and CI** **c. Include effect size with p-values and CI** **d. Include ARR/ABI and RRR/RBI with p-values and CI** **e. Include NNT and CI**	The statistical findings from the study showed at 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). 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). Circumferential measurements of the knee demonstrated no statistically significant differences between or within the two groups across any time intervals. 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 (ΔVAS^{CC} =-4.11, (CI=43.24, 58.31); ΔVAS^{C} =+15.67, (CI=38.14,64.42); p=0.023) and week 6 (ΔVAS^{CC} =-26.83; ΔVAS=+4.72; $p < 0.0001$). In the SF-36 cores, no statistically significant differences ($p > 0.05$) were detected between the C and the CC groups at all time intervals. 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 ($p > 0.05$). When evaluated by Lysholm scores, no statistically significant differences ($p > 0.05$) were detected between C and CC at all time intervals. These results indicate that there is an increase in

122. What is the meaning of these statistical findings for your patient/client's case? What does this mean to your practice?	compliance rates in the CC treatment group. These rates are only seen acutely at weeks 1 and 2. There was also a reduction in the use of narcotics at 6 weeks' post-op by the treatment group where over 83% of the the participants in the CC treatment group had discontinued their use. There were also better improvements in the VAS scores when the CC treatment group was compared to their pre-op VAS scores. This CC treatment would be feasible for patients that have a history of low compliance to cryotherapy and may have a more pain post-op. However, there was no significant difference in knee circumference or functional outcome measures. Therefore, the use of a CC device for every patient might lead to the same outcome as with using ice alone.
123. Do these findings exceed a minimally important difference? **a. If not, will you still use this evidence?**	There are no reported minimally important differences for the outcome measures analyzed in this study, besides the statistically significant p-values reported above. Without this data it is hard to determine if these results are significant for the patients. I still will use this evidence, because there was a decrease in pain, reduced narcotic consumption, and increase in compliance, when using a CC compared to the control. This can impact what type of device to utilize in a clinical setting.

Can you apply this valid, important evidence about an intervention in caring for your patient/client? What is the external validity?	
Appraisal Criterion	***Reader's Comments***
124. Does this intervention sound appropriate for use (available, affordable) in your clinical setting?	Yes, based on the results of this study there are some benefits to using a CDIC device over standard ice. This intervention is appropriate for use in a clinical setting. However, due to the inability to blind subjects, the limited number of objective measures and pt population. The same results may not be seen with the TKA patient. the researchers did not look at basic ice with compression. With its higher cost, minimal benefits, and more cumbersome application it might not be the best option for the patient.
125. Are the study subjects similar to your patient/ client? **a. If not, how different? Can you use this intervention in spite of the differences?**	No, 30 out of the 36 participants were male with a mean age of 29. They were also selected from a military population. This population was pretty homogeneous, they were all significantly younger, and the mechanism of injury (ACL reconstruction) differs from my patient. I will still be able to use this research when determining whether or not to use a CC device in clinic.
126. Do the potential benefits outweigh the potential risks using this intervention with your patient/client?	Yes, even though there are some contraindications to using a cold compression device including history of DVT, CHF, cardiac insufficiency, significant arteriosclerosis, or localized skin conditions. My patient does not have any of the contraindicated conditions, so the risk of using this device is very minimal.
127. Does the intervention fit within your patient/client's stated values or expectations? **a. If not, what will you do now?**	There is some efficacy in using a CC device. This intervention is appropriate for patients with a history of low compliance and low pain tolerance. However, the significant decrease in compliance

	at 6 weeks' post-op, no difference between knee circumference or functional outcome measures, and short term follow up does not convince me that this method is significantly better than ice alone. More research needs to be done to see if there are any long term benefits as well as significantly improve outcomes using a CC compared to standard ice and compression,
128. Are there any threats to external validity in this study?	Yes, the military population was fairly homogenous. These results might not be as reproducible to the general population undergoing ACL reconstruction. PT was also very accessible and centralized for these participants. The general population might not have as much access or the ease of access to physical therapy. There was no protocol for the parameters of compression or cooling using the CC device. With the variations in settings and no control for this, the reproducibility using the devices might be challenging.

The bottom line for this study is that there are some short term benefits when using the CC device. There was a significant reduction in narcotic consumption in the CC treatment group and there was a better improvement in VAS between pre-op and postop scores in the CC group.