CHAPTER **23**

THE EFFECT OF CRYOTHERAPY DEVICES IN THE POSTOPERATIVE SETTING

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INTRODUCTION

Cryotherapy, which refers to an application of cold to an injured area, is one of the most valuable and efficacious postoperative management modalities that affects multiple physiological processes for better patient recovery and comfort. Although its scientific significance in post-operative care was not extensively studied until recent years, it is one of the oldest therapies utilized in medicine. Today, there are many scientific theories that justify the application of cold to an injured part to help control edema, pain, muscle spasm, and tissue metabolism.

Cold therapy may entail many modalities to help cool an injured part, to the application of icepacks or ice cubes directly onto the skin or immersion of the injured part into cold water. Conversely, more sophisticated methods of cryotherapy have recently been popularized to provide a constant or intermittent therapeutic source. There are many commercially available cryotherapy devices that can be utilized in foot and ankle surgeries. The units consist of three main parts: a cooler, hose and bladder. The cooler contains ice water, which is delivered through the hose to the bladder. The bladder is applied to the area of interest or incorporated into the dressing. Despite these similarities among cryotherapy units, each device is unique in its mechanism of temperature regulation, structure of bladders, and water pump cycle pattern (Table 1). Therefore, outcome and application of each cryotherapy device may be different and should be considered before selection. Wilke et al studied these continuous-flow cryotherapy units in foot and ankle postoperative settings and concluded that they controlled pain, inflammation

Table 1

	Water flow pattern	Bladder filling mechanism	Temperature regulation
Iceman (DonJoy)	Continuous	Electrical pump	Capable via a dial from 0°C (32°F) to 40°C (104°F) but not recommended under 4 °C (39.2°F)
ArcticFlow (DonJoy)	Pulsatile	Gravity	Not capable of adjusting temperature
Ankle Cryo/Cuff (Aircast)	Pulsatile	Gravity	Not capable of adjusting temperature
Ankle AutoChills (Aircast)	Continuous	Electical pump	Not capable of adjusting temperature
EBIce (EBI)	Pump on for 52 seconds and off for 48 seconds at the coldest setting	Electical pump	Physician dependent via a dial from "cold" to "coldest"
PolarCare Cub (Breg)	Pulsatile	Hand pump	Not capable of adjusting temperature
PolarCare 300 (Breg)	Pulsatile	Hand air pump/ manual electrical pump	Temperature regulated at 8.3°C (47°F) - 10°C (50°F)
PolarCare 500 (Breg)	Continuous	Electrical pump	Capable via a dial from 1.7°C (35°F) to 21.1°C (70°F)

Table 1. Commercially available cryotherapy devices differ in their water flow pattern, bladder filling mechanism, and temperature regulation.

and blood loss. They also emphasized that caution should be taken since rare complications can be devastating.[1]

In this current study, both the efficacy and potential implications of three selected cryotherapy devices were investigated. The units were applied over standard post-surgical dressings as well as different layers of Jones compression bandages to mimic various postsurgical situations at our institution and in suspect for any of our colleagues. While a patient's subjective rating on these devices is important, knowing the physiological effects exerted by each cryotherapy device is also valuable to understanding the benefits provided by them. In order to understand those aspects of cryotherapy, a therapeutic and safe temperature range should be familiarized. This paper will focus on understanding the physiologic effects of cold therapy and its potential complications. We will also compare the different cryotherapy devices available and provide the reader with recommendations for safe and therapeutic settings in the utilization of cryotherapy devices in a postsurgical setting.

PHYSIOLOGIC EFFECTS OF COLD THERAPY

Cold affects the sympathetic nervous system as well as the spinal reflexes which triggers vasoconstriction to the affected areas resulting in hematoma reduction.[2] In addition, cold decreases vessel wall permeability, increases blood viscosity, and stimulates the hypothalamus for further vasoconstriction due to cold venous blood return.[3] Whether any or all of these physiological processes occur with any commercially available cryotherapy devices is unknown. Interestingly, Mora et al. discovered that pulsatile cold compression achieved significant ankle circumference reduction in patients after ankle fracture, when compared to patients treated with splinting and elevation alone.[4] A similar result was obtained by Scheffler et al. in human subjects with compressive cryotherapy using Cryo/Cuff".[5] Furthermore, Stockle et al. suggested that continuous cryotherapy devices reduced tissue swelling in the lower extremity more effective than the simple icepack application.[6]

Temperatures at which soft tissue edema reduction is optimally achieved is not well documented. In a study done by McMaster and Liddle using a New Zealand white rabbit model, a group of injured limbs submerged into 30°C (86°F) water had the greatest edema reduction when compared with limbs submerged in 20°C (68°F) water and left under ambient room temperature.[7] They concluded that cooler temperatures or lengthened application times may be harmful. To support McMaster and Liddle's conclusion, another study done by Matsen et al showed increased postfracture swelling in rabbits' hind limbs when the temperature range was from 5°C (41°F) to 15°C (59°F).[8] Whether these studies apply in a clinical setting remains uncertain. These studies do suggest that extreme temperatures in either direction do not provide edema reduction. It is known that high temperatures lead to vasodilatation and accumulation of fluid, therefore it is imperative to maintain a specific temperature range for edema reduction in the postoperative period.

Cold also aids in pain reduction by decreasing the nerve conduction velocity.[1-3] The numbness that people experience in an extremely cold environment can certainly mask pain; however, there is no study to the authors' knowledge that scientifically demonstrates that commercially available cryotherapy cuffs would achieve pain reduction by slowing down nerve conduction. According to Bugaj, the analgesic effect of cold would not be achieved unless the skin temperature is under 13.6°C (56.5°F).[9] Olson and Stravino also indicated that the complete nerve conduction disruption would not be achieved until the temperature goes below the range of 10°C (50°F) to 15°C (59°F).[3] Before the temperature reaches this level, Weresh states that the nerve conduction is gradually suppressed starting at 25°C (77°F).[10]

It is commonplace in foot and ankle surgery to prescribe muscle relaxants for muscle and tendon pathology. Cold therapy can also be used to decrease muscle spasticity, which may lead to discomfort and pain in the postoperative setting.[1] Physiologically, tone of muscles is governed by muscle spindles, which detect changes in muscle fiber lengths, and send signals to adjust muscle tension in an attempt to prevent themselves from being permanently damaged. Inhibitory and excitatory neurons act in synch to avoid imbalance in such a delicate equilibrium. When the higher nervous system fails, unopposed excitatory neurons cause muscle spasticity. Muscle spasticity will subsequently lead to tissue ischemia, reduced venous return and ultimately, pain from toxic byproducts in the tissue. These phenomena are believed to be prevented when the temperature is below 25°C (77°F).[10]

Cooling can also prevent tissue hypoxia at a microscopic level.[1-3] For every 10°C drop in temperature cellular chemical reactions in general slow down two fold, which results in lower oxygen requirements in the tissue.[3] This cascade of events is clinically confirmed by the fact that oxygen saturation of venous return is increased in cold environments (less oxygen is utilized by peripheral organs). After a traumatic event, injured vascular structures cannot provide the adequate amount of oxygen

required by normal healthy tissues to survive. Subsequently, healthy tissues die from hypoxia unless either an additional source of oxygen is provided or oxygen demand is reduced in the traumatized areas. Cold therapy application provides significant benefit to the local tissues by lowering oxygen demand and in turn results in less tissue hypoxia.

PYSIOLOGY OF COLD INDUCED INJURIES

Though beneficial and simple, application of cold has many side effects if not utilized properly. Such complications include: frostbite, frostnip, chilblain, trench foot, immersion foot, nerve palsy, sensitivity to cold, joint stiffness, pain and soft tissue swelling.[1-3,11,12]

Long durations of cold exposure, even above freezing temperatures between 1.6°C (34.9°F) and 4.4°C (39.9°F) could result in frostbite..[13] While scientists have yet to determine the exact mechanism of frostbite injury, it is now generally accepted that ischemia resulting from alteration in vascular physiology is responsible for tissue necrosis.[14] The body's temperature regulating mechanisms protect deep tissues by sacrificing superficial tissues. This process is maintained through the numerous arteriovenous shunts that allow heat to be given off as blood flows from superficial to deep. It is this process that effectively warms the deep tissues.[15]

After prolonged cold exposure, these shunts close, leading to vascular injury. With extreme cold exposure, blood viscosity increases, leading to cessation of capillary circulation and occlusion of blood vessels. This ultimately leads to hypoxia, ischemia and tissue necrosis.[16]

Another proposed mechanism of tissue necrosis is the direct freezing of the tissues.[15,17,18] Direct freezing consists of four separate progressive phases of tissue injury: pre-freeze, freeze-thaw, vascular stasis and the ischemic phase. During the pre-freeze phase, which occurs at temperatures between 2.7°C (36.9°F) to 10°C (50°F) patients experience edema and diminished sensation. The most damaging phase, the freeze-thaw phase, has been shown to occur at temperatures between -15°C (5°F) and -6.7C (20°F).[16] During this phase extracellular ice crystals form, which creates an increase in the osmotic pressure and allows intracellular fluid to be drawn out of the cell. This results in cellular dehydration which, in turn, leads to cell death. In addition, there are concurrent cycles of vasoconstriction and vasodilation as the body attempts to rewarm itself. This series of cycles is referred to as the Hunting reaction, which results in partial thawing and subsequent refreezing of tissue, a process that has been shown to lead to increased tissue damage. While the Hunting reaction is a defensive mechanism that has been known to start when the temperature decreases below 25°C (77°F), it is not thought to cause increased tissue damage until the temperatures decrease to the level of the freeze-thaw phase.

The vascular phase (characterized by plasma leakage, stasis, coagulation and vasospasm) occurs as ice crystals continue to develop in the extracellular fluid. The final phase of direct freezing is the ischemic phase, resulting in tissue necrosis, thrombosis and autonomic dysfunction.[16]

MATERIALS AND METHODS

There were three cryotherapy devices utilized in this study: Iceman™ Model 1100 Cold Therapy system (DonJoy Orthopedics™, Vista, CA), EBIce® (EBI®, Parsippany, NJ) and Ankle Cryo/Cuff® (Aircast® Incorporated, Summit, NJ).

DonJoy™'s Iceman™ represents a continuous cryotherapy device. It has an electrical pump that mechanically delivers water through the hose and into the bladder (Figure 1A). The electrical pump is found within the cooler and continuously delivers cold water into the bladder. The circulation of water keeps the lower extremity cool during the entire cryotherapy as long as the cooler is refilled with ice water every three hours. Also, the unit has a dial on the hose, which connects the cooler and bladder, to adjust water temperature. Next to the dial there is a temperature indicator ranging from 0°C (32°F) to 40°C (104°F). However, the company does not recommend setting the temperature below 4°C (40°F).

EBIce® delivers water in a continuous fashion via its electrical pump. It also has a temperature control dial that has settings ranging from "cold" to "coldest" (Figure 1B). Depending on the setting, the interval of pumping water into the bladder varies. For example, at the least cold setting, the pump is only on for 9 seconds out of every 100 seconds; while at the coldest setting, the pump is on for 52 seconds out of every 100 seconds. Therefore, the device circulates water in an intermittent fashion although the device is continuously on.

Cryo/Cuff® delivers cold water into its bladder utilizing gravitational force (Figure 1C). Manual elevation of the cooler above the bladder draws the cold water into the bladder. The company's recommendation is repeat this cycle every 2 to 3 hours. There is no electrical pump attached to this device or a temperature-adjusting dial. Unlike others, this device provides 30-35 mmHg of compression to the affected area.[4,19]

A thermocouple device for measuring surface skin

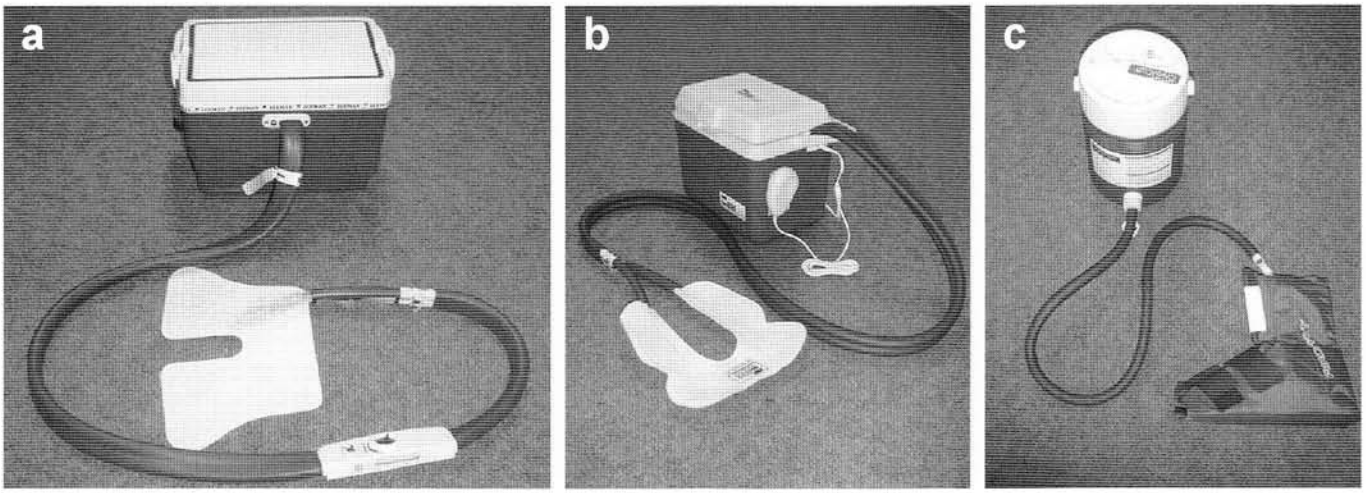

Figure 1. Three commercially available cryotherapy devices are investigated in this study: a) DonJoy™'s Iceman™ b) EBI®'s EBIce® c) Aircast®'s Cryo/Cuff®.

temperature of the subject was utilized. The authors chose the HH508 Digital Thermometer® (Omega®, Samford, CT) based on its ability to precisely measure skin temperature with minimal variance (Figure 2). The unit is capable of being operated in an ambient temperature of 0°C (32°F) to 50°C (122°F) and measuring the temperature ranges from -200°C (-328°F) to 1372°C (1999°F). The accuracy in the temperature range of this study's interest is ± 0.1% of the reading + 1°C. This temperature-measuring device has wire probes that can easily be inserted under the dressings.

The test subject chosen for this study was a thirty year old male in excellent overall health with no past medical history. He had no sign of neurovascular compromise-normal pedal pulses, capillary fill time, and epicritic sensation. The subject was not a smoker and had no risk factors for peripheral vascular or vasoconstrictive disease. The subject was placed in the supine position with his extremities elevated utilizing two pillows. The temperature-measuring probe was then placed on the midfoot dorsally in the area of the lateral cuneiform and secured with paper tape. In order to mimic the post-surgical scenario, three layers of 8-ply, 4" x 4" Gauze Sponges (#2318 Johnson & Johnson Medical, Arlington, TX) were placed over the midfoot above the temperature-measuring probe. One roll of 3" x 75" Sof-Kling™ (#6993 Johnson & Johnson Medical, Arlington, TX) conforming gauze bandage followed by one 4.5" x 4.1 yard Kling™ fluff roll (#6930 Johnson & Johnson Medical, Arlington, TX) were applied to cover the entire foot from the proximal digits to the level of the ankle.

Due to the design variations between the three devices, In Group I, The Iceman™ and EBIce® devices were applied over the dressings mentioned above and held in place with a Swift Wrap® Elastic Bandage (Medline Industried, Inc., Mundelein, IL). The Ankle Cryo/Cuff®

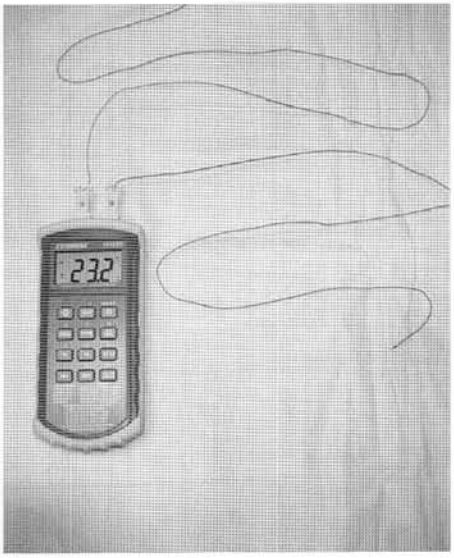

Figure 2. HH508 Digital Thermometer® (Omega®, Samford, CT) was utilized to measure the surface skin temperature.

was placed over the top of the dressings and the Swift Wrap® Elastic Bandage. The skin temperature was obtained immediately after the application of the dressings. The ice cubes were put in the cooler of each cryotherapy device to the level of company recommendation, and tap water was poured into the cooler. The water was then cooled for 10 minutes and the units were set at the lowest temperature before starting the experiment. Cryo/Cuff® was manually re-circulated every 15 minutes to achieve the coldest possible temperature against the company's recommendation (which was to re-circulate the water every 2 - 3 hours). The skin temperature was then recorded every 15 minutes for 180 minutes starting at the initiation of cryotherapy.

In Group II, one layer of Jones compression bandage, which consisted of two 4" x 4-yard Specialist® cast paddings (#9044 Johnson & Johnson Orthopaedics, Raynham, MA) and a 6-inch Swift Wrap® Elastic Bandage applied from the digits to the tibial tuberosity, was applied over the dressings utilized in Group I. The Iceman™ and EBIce® devices were held in place over the Specialist® cast paddings underneath the 6-inch Swift Wrap® Elastic Bandage, whereas the Cryo/Cuff® was placed over the 6-inch Swift Wrap" Elastic Bandage, and the skin temperature was recorded in the same fashion described above.

In Group III, a second layer of Jones compression bandage was applied over the dressing model of Group II, the devices were applied on top of this layer in the same method as described in Group II. The temperatures were again recorded in the same manner.

RESULTS

A summary of the temperature recordings of all three units in Groups I-III is shown in Table II and the temperature progression curve is shown in Figure 3a-c. In Group I, DonJoy™s continuous cryotherapy device was discontinued due to intolerable pain and parasthesias experienced by the subject at 105 minutes of the trial. The skin temperature reading at this point was 14.2°C (57.6°F). Extensive forefoot erythema and delayed capillary fill time of the digits (11 seconds) was noted prior to discontinuation of the Iceman™ unit. Both EBIce® and Cryo/Cuff® were tolerated for the full 180 minutes and the final skin temperatures were noted to be 15.8°C (60.4°F) and 18.5°C (65.3°F), respectively. However, the temperature gradient was still declining at the end of each trial at 180 minutes.

In Group II, the subject was pain free and the temperature depression leveled off before the end of the trials in all three units. Both Iceman™ and EBIce® were able to keep the skin temperature below 30°C (86°F) for the length of cryotherapy trial. Cryo/Cuff® initially lowered the skin temperature, however, the skin temperature rebounded back to the initial starting temperature (31.6°C/88.9°F) at 180 minutes.

In Group III, the skin temperatures in all three cryotherapy units were higher than the initial readings at the end of each trial. The difference in temperature depression between the units was minimal.

DISCUSSION

Determination of an appropriate therapeutic temperature range for effective cryotherapy application certainly is not clear cut. It is evident that diminished muscle spasticity and suppression of nerve conduction (which is beneficial in the postoperative period) begins when the temperature drops below 25°C (77°F). Exact therapeutic temperatures

Table 2

	Iceman						EBIce						Cryo/Cuff					
Group	**I**		**II**		**III**		**I**		**II**		**III**		**I**		**II**		**III**	
Time (min)	**Temp (°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**	**(°C)**	**(F°)**
0	32.6	90	32.0	89	28.7	83	32.2	89	31.8	89	32.3	90	28.7	83	31.6	88	32.6	90
15	27.5	81	30.0	86	27.9	82	27.4	81	30.3	87	31.5	88	26.8	80	30.0	86	33.6	92
30	23.7	74	29.5	85	27.8	82	25.2	77	29.9	85	30.6	87	26.3	79	28.7	83	33.2	91
45	21.3	70	28.5	83	27.7	81	23.6	74	29.1	84	29.7	85	25.5	77	27.4	81	32.4	90
60	19.1	66	27.4	81	27.4	81	21.5	70	27.4	81	29.5	85	24.4	75	27.4	81	32.9	91
75	16.8	62	26.5	79	27.7	81	20.1	68	27.2	80	29.4	84	23.1	73	27.4	81	32.7	90
90	15.1	59	25.9	78	29.9	85	18.4	65	26.8	80	29.4	84	22.3	72	27.4	81	32.3	90
105	14.2	57	25.7	78	30.8	87	18.0	64	26.5	79	30.9	87	22.1	71	28.8	83	32.3	90
120			26.2	79	31.2	88	17.7	63	26.5	79	31.6	88	21.2	69	29.1	84	32.3	90
135			27.1	80	31.9	89	17.2	62	27.1	80	32.7	90	20.6	69	29.9	85	32.3	90
150			27.2	80	32.0	89	16.3	61	26.8	80	33.3	91	19.6	67	30.7	87	32.1	90
165			28.0	82	32.6	90	16.1	60	28.0	82	33.5	92	19.0	66	31.6	88	33.0	91
180			29.0	84	32.7	90	15.8	60	29.6	85	33.6	92	18.5	65	32.1	89	32.6	91

Table 2. A summary of the surface skin temperature progression with application of three cryotherapy devices over different layers of dressings. The cryotherapy units were applied over the standard surgical dressing in Group I, over one layer of Jones compression bandage in Group II, and over two layers of Jones compression bandage in Group III.

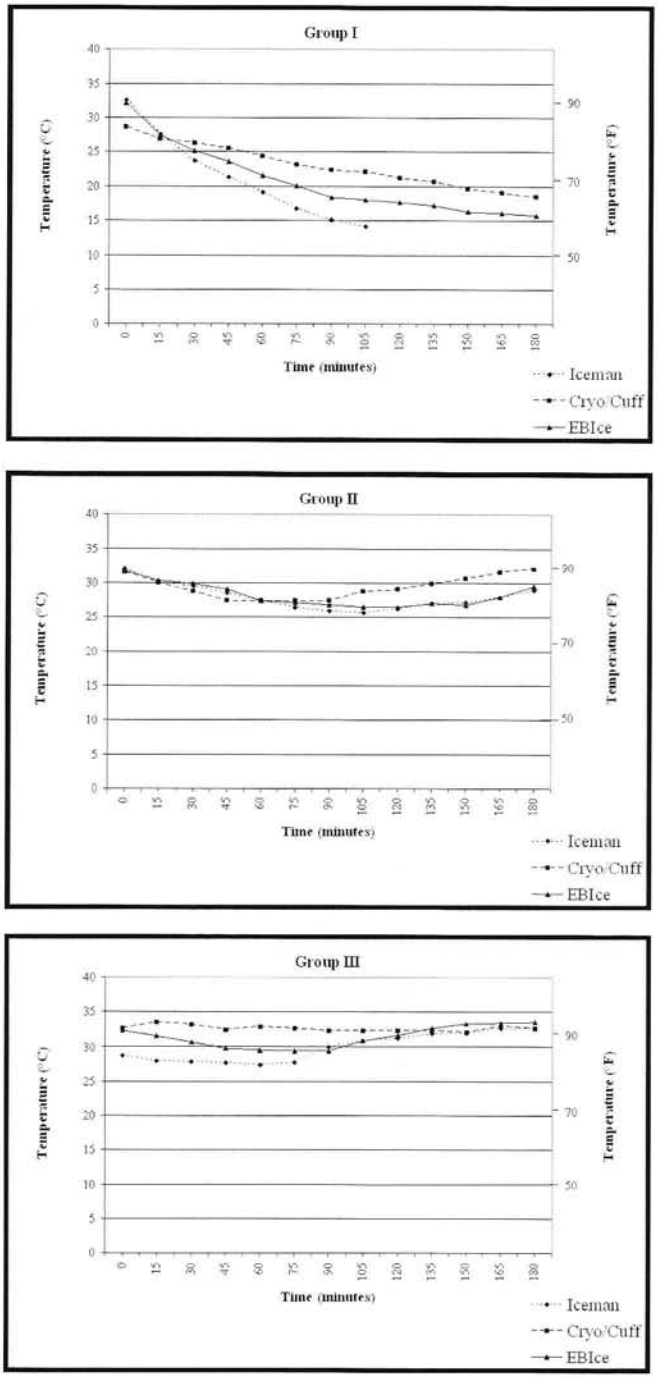

Figure 3. The surface skin temperature progression curves under A) no Jones compression bandage (Group I), B) one layer of Jones compression dressing (Group II), and C) two layers of Jones compression dressing (Group III).

that result in edema reduction are not easily determined, however, one could assume (based on results from Matsen et al. and McMaster and Liddle's conclusions) that edema reduction is best achieved when the temperature is maintained between 20°C (68°F) and 30°C (86°F). Interestingly, the subjective information received from the test subject throughout the study indicated that the most comfortable period of testing (the temperatures at which the subject felt coolness from the cryotherapy units, without pain or discomfort) was actually between 23°C (73°F) and 30°C (86°F). Once the skin temperature rose above 30°C (86°F), the subject relayed his extremity felt "hot" and actually began to perspire. When the temperature fell below 23°C (73°F) with the Iceman™ device, the subject began to feel discomfort which became intolerable at 14.2°C (57.6°F) and required discontinuation of the unit. The subject did not experience discomfort with the EBIce® and Cryo/Cuff® until the temperatures reached 18°C (64°F). The subject relayed that discomfort began at a higher temperature with the Iceman™ simply because the continuous flow of the unit resulted in an earlier intolerance to cold, whereas the intermittent flow devices were easier to tolerate. Based on the subjective information relayed by the test subject combined with the data given above, the authors feel they can comfortably give an adequate recommended therapeutic temperature range of 20°C (68°F) to 30°C (86°F) for intermittent cryotherapy units, and 25°C (77°F) to 30°C (86°F) for continuous units.

In this study the Iceman™ was the only device that required discontinuation. Keep in mind that a patient in a suboptimal state, such as those with peripheral vascular disease, vasospastic disease, neuropathy, or simply a patient in their postoperative period with a local anesthetic nerve block and/or taking oral narcotic analgesics are more prone to complications. The temperature reached by this device (14.2°C (57.6°F)) was not only capable of complete interruption of nerve conduction, but also it is possible to increase the local tissue edema as suggested by Matsen's as well as McMaster and Liddle's studies.[7,8] None of these devices reached the temperature that is suggested to induce crystallization of extracellular fluid for direct damaging of the tissues (i.e. frostbite).

Over one layer of Jones compression bandage, Iceman™ and EBIce® were better able to control temperatures between 25°C (77°F) and 30°C (86°F) which is still within the temperature range at which edema reduction is thought to be attained, however, neither device was able to reach below 25°C (77°F) which is the level where nerve conduction would be suppressed to achieve reduction of muscle spasm or pain signal transmission. The Cryo/Cuff® was unable to keep temperatures below 30°C (86°F). These findings are consistent with a study done by Weresh et al., who demonstrated that temperatures lower than 25°C (77°F) were not achieved by the application of icepacks over one layer of Jones dressing within a 90-minute period.[10]

Over two layers of Jones compression dressing, no device reached the therapeutic level. Because the skin temperature was higher than initial readings, nerve conduction would not be affected by these devices nor would reduction of metabolism in the tissue. Amount of edema reduction would not be any greater than without utilization of cryotherapy for the same reason. Jones compressive bandages are poor conductors of cold,[10] and if two layers are applied, the cryotherapy device is not be able to achieve a therapeutic level.

It also should be noted that upon discontinuation of the devices, the Iceman™ and EBIce® devices developed enough condensation from their bladders to actually make the dressings damp to the touch. The Cryo/Cuff® did not exhibit any condensation and upon discontinuation of the device, the dressings were completely dry.

CONCLUSION

Cryotherapy is an effective and simple method of postoperative management for ease of patient recovery and comfort. It is usually used in conjunction with other postoperative regimens, such as compression dressings, elevation of the extremity and pharmacological management. Newer cryotherapy devices can be very effective at minimizing postoperative pain, swelling, muscle spasm and discomfort, when utilized in the appropriate manner. It is therefore important for a health-care provider to familiarize him/herself with each device's characteristics to optimize the postoperative management via cryotherapy. Furthermore, one has to remember that patient compliance, underlying medical conditions and effects on adjunctive postoperative regimens were also contributing factors that affect the outcome of successful cryotherapy. Understanding these factors would not only minimize complications due to cryotherapy, but also optimize patient recovery from foot and ankle surgeries.

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