CLINICAL EVALUATION OF VASOPNEUMATIC CRYOTHERAPY DEVICES

Background

Patients who experience musculoskeletal injuries or who are recovering from various orthopedic procedures are typically advised to follow the R.I.C.E. method (rest, ice, compression, and elevation) to aid in healing. Current literature on the use of cryotherapy (also known as cold therapy and ice therapy) suggests that cryotherapy is beneficial in treating soft tissues injuries and post-surgical trauma [1,2], and it has been shown to reduce pain and swelling in patients after surgery [1-11]. Similarly, the clinical usefulness of compression to reduce swelling and edema, aid recovery, and prevent venous thromboembolism (VTE) in this patient population is also well documented [3-7]. Three studies specifically address the use of compression after knee surgery [5,6,7] and results suggest improved and accelerated patient outcomes (i.e., subjective pain, medication intake, swelling, range of motion, blood loss) with compression therapy. Additionally, the increased tissue tension caused by swelling is an important factor in causing pain, therefore if swelling can be minimized pain will be reduced[11].

Although both cryotherapy and compression are universally accepted as necessary treatment following musculoskeletal injuries or surgery, there is limited literature on the use of combination therapy utilizing both active, continuous cold, and intermittent pneumatic compression on post-operative measures in patients. This combination approach to injury and post-operative recovery will be referred to as vasopneumatic cryotherapy in this paper.

A single study specifically examined the use of continuous-flow cold therapy after total knee arthroscopy (TKA) and found that vasopneumatic cryotherapy is advantageous to healing. At 1-week post-operation, it provided significantly better results in visual analogue pain scores, analgesic use, hemovac output and blood loss, range of motion, and wound healing[12].

The following document summarizes the applications and clinical value of vasopneumatic cryotherapy for injury or post-operative recovery.

Principles of vasopneumatic cryotherapy

Unlike standard cryotherapy, medical devices that employ vasopneumatic cryotherapy allow for temperature adjustments based on clinician and patient preference. This function helps to avoid tissue damage and offers deeper, precise, and more consistent cooling without the pain and discomfort associated with ice packs.

Compression helps to minimize the swelling and consequent edema associated with injuries. Standard compression aids (e.g., elastic bandages) can only provide static compression. Vasopneumatic cryotherapy devices provide intermittent, or cyclical compression, which is preferable to static compression as it more closely mimics the muscle contractions that the body uses to force tissue debris and excess fluid out of the affected area and into the lymphatic system for proper drainage.

Intermittent pneumatic compression has been found to prevent deep vein thrombosis (DVT), for example in TKA patients whose incidence rate for DVT without some form of prophylaxis is between 40-80 percent [13] .

Clinical applications for vasopneumatic cryotherapy

Vasopneumatic cryotherapy is used to improve outcomes and to speed recovery following various injuries:

- Ankle: chronic or acute injuries such as sprains, fractures, contusions, Achilles tendonitis; post-operative symptoms following ankle, hind- or mid-foot, or other orthopedic surgery (including arthroscopic procedures)
- Calf/Shin: chronic or acute injuries such as stress fractures, shin splints, fibular fractures, plantaris tendon ruptures, inflammatory arthritis, contusions
- Knee: chronic or acute injuries such as sprains, fractures, contusions; post-operative symptoms following ligament reconstruction, joint replacement, fracture repair, meniscectomy, or other orthopedic surgery (including arthroscopic procedures)

- Back: chronic or acute conditions including low back pain, sprains, contusions, facet syndrome; post-operative symptoms following spinal fusion or other orthopedic surgery
- Shoulder: chronic or acute injuries such as tendonitis, bursitis, fractures, contusions; post-operative symptoms following rotator cuff repair, acromioplasty, total shoulder replacement, Mumford procedure, or other orthopedic surgery (including arthroscopic procedures)
- Elbow: chronic or acute injuries such as tennis or golf elbow, lateral or medial tendonitis, forearm fractures, contusions; post-operative symptoms following total elbow replacement, fasciotomy, or other orthopedic surgery (including arthroscopic procedures)

Concomitant and sequential use with other treatments

Vasopneumatic cryotherapy can be used as part of standard treatment programs that can be customized by a physician, physical therapist, or user for various time, temperature and compression settings. Vasopneumatic compression treatment can be used in protocols that include Continuous Passive Motion (CPM) devices, Electrical Stimulation, and other devices or treatment modalities. Vasopneumatic cryotherapy should not be used in addition to another cryotherapy regimen.

Patient contraindications

The major precaution with cryotherapy is to avoid tissue or nerve damage from improper placement or prolonged use of cooling. Because cold reduces local metabolic rates and blood supply, it also may slow wound healing. Pressor responses to cold aggravating cardiovascular disease and the effects of direct and consensual vasoconstriction in ischemic limbs also should be considered. More specific concerns are exacerbation of symptoms in patients with Raynaud's disease, vascular impairment (eg, from prior frostbite, diabetes, or arteriosclerosis), or compromised local circulation (including localized compromise due to multiple surgical procedures). Cold hypersensitivity and urticaria are also rare but potential allergic reactions.

Vasopneumatic compression must be avoided during the acute stages of inflammatory phlebitis or in patients with any history or risk factors for deep vein thrombosis or pulmonary embolus, including prolonged bed rest. Patients with any history of cardiac insufficiency or congestive heart failure (with associated edema in the extremities or lungs) or those with significant arteriosclerosis or other vascular ischemic disease, as well as those with any localized skin condition (eg, dermatitis, vein ligation, gangrene, skin graft) also should avoid vasopneumatic compression. Additionally, any patient with a condition in which increased venous or lymphatic return is not desired (eg, carcinoma in the affected extremity) should avoid this therapy.

Vasopneumatic cryotherapy should always be used with caution in children, diabetics, incapacitated patients, or those persons with an extremity that has neurologic impairment or compromise. Persons with cognitive disabilities or communication barriers should use this therapy only when closely monitored by a licensed healthcare professional.

During the course of therapy, patients should monitor their skin for any burning, itching, increased swelling, or pain. If any of these signs present, or any changes in skin appearance occur (eg, blisters, increased redness, discoloration, or other noticeable skin changes), patients are advised to discontinue use and consult a physician.

Game Ready™ Accelerated Recovery System

The Game Ready device is a vasopneumatic compressor with cryotherapy and consists of various soft wraps and a computer-controlled control unit. The wraps are made from flexible fabric and are ergonomically designed to fit various body parts and can be secured easily with a hook and loop fastener. The wraps fit snugly to apply intermittent compression and cryotherapy at and around the injured area.

It is the Game Ready Accelerated Recovery System's unique ability to apply intermittent compression with continuous cryotherapy that speeds injury recovery and rehabilitation.

To operate the system, the control unit reservoir is filled with ice and water and the unit is plugged into a wall outlet or the portable battery pack. A wrap is applied to the injured area and connected to the control unit. The wrap is inflated and deflated on a pre-set cycle, while simultaneously ice-cooled water is circulated through it, over the course of a standard treatment program that can be customized by a physician, physical therapist, trainer, or user for various time, temperature, and compression settings.

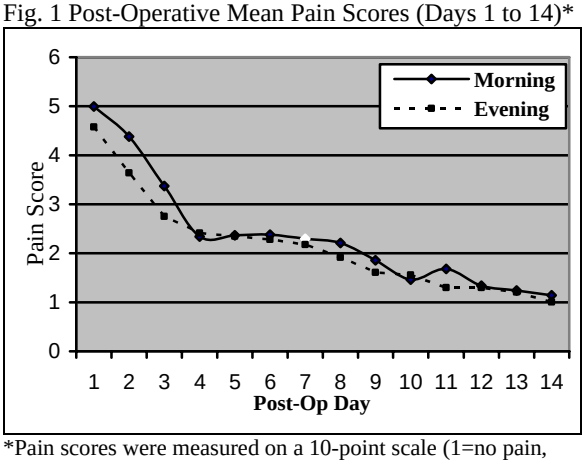
Game Ready's vasopneumatic compressor with cryotherapy provides:

- Cooling of injured areas intended to reduce pain and muscle spasms and help prevent further tissue damage
- Intermittent compression intended to aid in removal of swelling and edema from the site of injury
- Controlled cold therapy temperature range to maximize effectiveness and help prevent tissue damage from freezing
- Ergonomically designed wraps made to fit various body parts for effective coverage and increased comfort
- Easily adjustable temperature, pressure, and treatment time settings
- Portability: the system can be used in the hospital or at home, as well as on the field, or while traveling (bus, car, plane)

Game Ready Clinical Experience

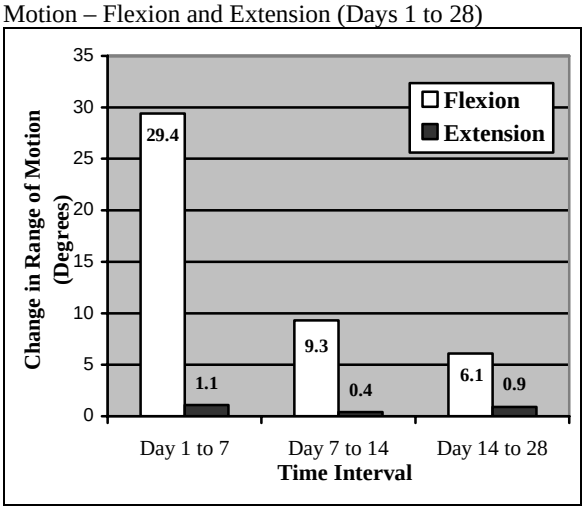
In the clinical setting, the Game Ready Accelerated Recovery System has proved to be effective in providing positive patient outcomes. In a prospective, single-site study that evaluated the therapeutic effects of the Game Ready system following arthroscopic knee surgery, patients who used the Game Ready system for up to four weeks experienced a marked reduction of knee pain and a marked increase in knee range of motion (extension and flexion). After 14 days of treatment, both morning and evening pain scores decreased significantly by an average of 3.9 points (on a 10 point scale). Notably, evening pain scores decreased sharply after only 4 days of treatment (Fig 1). After 28 days of treatment, knee extension and flexion increased by 2 degrees and 47 degrees, respectively (Fig. 2). The greatest increase in both flexion and extension was seen after only 7 days of treatment, which is a clinically significant increase for both of these outcome measures.

Fig. 1 Post-Operative Mean Pain Scores (Days 1 to 14)*



*Pain scores were measured on a 10-point scale (1=no pain, 10=severe pain). Note pain scores were not available on the morning of day 7.

Fig. 2 Post-Operative Average Change in Range of Motion – Flexion and Extension (Days 1 to 28)



Based on preliminary data from this study as well as anecdotal evidence from hundreds of prescribing clinicians, the Game Ready Accelerated Recovery System provides improved outcomes over traditional therapy (ice and wraps)

for patients who experience a significant amount of post-operative pain and swelling.

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