

Advantages of Cooling Phase Change Material over Ice and Ice-based Products for Patients and Athletes

<u>Cold therapy is regularly prescribed by medical professionals as a therapeutic modality</u> to alleviate physiological and functional deficits and to induce analgesia and relieve pain following acute soft-tissue injuries and recovery from surgical procedures [1,2]. Similarly, cold therapy is popular with both trained and recreational athletes as they are presented with the challenge of dealing with exercise induced muscle damage and muscle soreness following moderate or strenuous exercise programs [3-5].

<u>The benefits of cold therapy have been well-documented by extensive research studies</u> that have explored the ability of cold therapy to reduce edema, inhibit hematoma formation, diminish the inflammatory response following trauma, reduce muscle spasm and provide an antinociceptive effect [6-10]. Localized cooling has benefits following orthopedic surgery and in sports medicine to reduce swelling, pain, inflammation, metabolism, muscle spasm, and bleeding [11,14,21]

For many decades, repeated rounds of short-duration treatment with ice have been typically recommended for the first 48 hours after an injury or surgery to provide comfort and to reduce swelling of the affected area and provide pain relief to the patient.

However, growing evidence has highlighted that traditional cold therapy (*e.g.*, topically icing the injured area) may not be helpful but rather act as a barrier to recovery process. [2,8,10,11].

<u>The known risks of using ice-based products have been well documented</u> and include skin burns, frost bite, tissue and nerve damage. Ice-based products are recommended to be applied only intermittently to minimize patient risk and discomfort. Further, research now shows that extremely cold treatment modalities, like ice and other cryotherapies, can actually have negative implications for patients.

- 1) One of the primary outcomes of localized cooling is vasoconstriction of the underlying skin and tissues [12-16] which may lead to ischemia (reduced blood flow).
- 2) Extended bouts of cold-induced vasoconstriction may lead to nonfreezing cold injury to the patient [17-19] resulting in tissue death or even permanent nerve damage.
- 3) Additionally, reperfusion injury has been observed when the affected tissues warm and blood flow is reestablished [11,20].

Finding 1: Ice is too cold. 11-15°C (52-59°F) is more beneficial for cool therapy.

With the growing realization that ice may not be the optimal therapeutic modality, many studies focusing on different cold therapy approaches ranging from bags of ice, to electrically powered continuous cold therapy devices and cold-water immersion protocols have been explored.

A systematic review of studies has identified:

- 1) Temperatures between 11-15°C (52-59°F) were more beneficial than more severe cold temperatures < 10°C for the management of muscle soreness [22]
- 2) 15°C is optimal for healing and patient satisfaction following surgery [23]. Specifically, cooling at 15°C compared to icing or lower temperatures resulted in reduced swelling by an average of 28%, reduced reported pain by 43%, and improved patient satisfaction by 38% across the first 4 days. Importantly, cold therapy has been shown to reduce patients' post-surgical need for opioids [24].

Finding 2: Ice- and water-based cooling therapies have significant drawbacks

Many studies demonstrate the advantage of 15°C utilized cold-water immersion (CWI) or circulating ice-water to deliver cold therapy at a desired temperature. Although clearly beneficial for the treatment of EMID and muscle soreness, CWI has many significant drawbacks including:

- 1) a central effect on lowering core temperature and heart rate
- 2) a requirement for large immersion tubs and significant volumes of water
- 3) the patient experience: discomfort which negatively impacts treatment duration
- 4) a disruption to normal activities limits opportunities for treatment [especially recreational athletes]

Circulating water systems are a slight improvement over icing. However, these systems still suffer challenges, including:

- 1) difficulties regulating the temperature when using ice as its cooling medium; hard to attain or maintain the optimum therapeutic target of 15°C
- 2) systems tether the patient during use, limiting mobility with cumbersome tubes, wires and cords
- 3) risk of patient misuse; ice burn and tissue damage

Finding 3: Cooling PCM Safe for Prolonged Use / Effective for Pain Management

To address the limitations of ice-based devices, Phase Change Materials (PCMs) have been investigated as a cooling modality that can extend the duration of cryotherapy exposure while allowing the patient or athlete to continue with normal activities. Studies found:

- 1) Cryotherapy with PCMs designed to provide cooling at the optimal 15°C temperature have achieved reductions in the magnitude of intramuscular temperature comparable to 15 min of CWI [25] and can be tolerated for prolonged durations (3–6 hours).
- 2) Prolonged PCM cooling has been effectively used for reductions in soreness and strength loss on the days after eccentric quadriceps exercise in recreational athletes [26] and after a professional soccer match [27] when applied for 6 and 3 hours, respectively.
- A recent study provided further evidence of the beneficial effect of treatment at 15°C with PCM on strength loss and soreness and in addition showed that cooling PCM does not hinder the adaptive response of athletes to a subsequent round of strenuous exercise [28].

Advantages of ONYX COOL wearable PCM for Patients and Athletes

A clinical study conducted by Englewood Hospital in New Jersey compared the post-operative experience of patients using wearable PCM cooling therapies to those using circulating water devices. Patient satisfaction scores for post-op recovery with the cooling PCM knee, hip or back devices were 93%, 31% higher than patients who used circulating water devices. In addition, patients using the cooling PCM had better pain management scores and use of pain medications decreased.

Safe and Effective

ONYX COOL wearable PCM delivers cool therapy at the optimum healing temperature of 15°C (58°F) which creates a comfortable, analgesic effect to relieve pain and swelling.

- 1. Normal blood flow, continuous circulation helps heal tissues; no vasoconstriction or ischemia risk
- 2. Devices can be worn directly on the skin. No risk of frostbite or soft tissue burn.
- 3. Safe for prolonged, continuous use

Faster, More Satisfactory Recovery

- 1. PCM therapies allow for greater mobility while still experiencing cool therapy [26-28].
- 2. Cool comfort and ease of use drives patient compliance, which accelerates healing
- 3. Pain medication decreases
- 4. Patient satisfaction increases

SUMMARY: ONYX COOL PCM is safer than ice and ice-based cryotherapies. Cooling PCM relieves pain while continuous blood flow helps heal tissues. Patient comfort drives patient compliance, which accelerates the recovery and healing process.

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