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Original Research

The Effects on Knee Swelling, Range of Motion and Pain using a Commercially Available Hot/Cold Contrast Device in a Rehabilitation and Sports Medicine Setting

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Background and Purpose

Contrast therapy consists of alternating thermotherapy and cryotherapy repeatedly to assist in the management of acute, subacute, and chronic musculoskeletal conditions. This has been utilized for several decades with good to excellent subjective and objective results reported for patients with swelling (acute to chronic), pain, and loss of motion. Typically, the intervention is performed by either the use of a hot and cold whirlpool or by applying hot and cold packs which can be very time consuming and labor intensive. The purpose of this study was to determine the efficacy of a single treatment of the Hyperice X system in reducing knee joint pain, swelling and stiffness in active patients and young injured athletes. A secondary purpose was to measure patient satisfaction with the use of the device.

Subjects

Fifty subjects (34 males and 16 females) with a mean age of 22.2 +/- 4.9 yrs (ranging from 17 to 45 yrs of age) were recruited. Subjects presented with various types of knee pain, both non-operative and operative, secondary to ligamentous, tendinous, cartilage, muscle, and/or meniscus pathology. The subjects were in various stages of rehabilitation with six in the acute stage, 24 in subacute stage, and 20 in the chronic stage. The subjects participated in a variety of different sports at various levels of competition ranging from recreational to professional.

Methods

Subjects were recruited from one of two centers: an athletic training room or an outpatient sports medicine rehabilitation center. They were evaluated for baseline pain using the visual analog scale (VAS),verbal patient satisfaction on a scale of 1-10, verbal assessment of knee tightness, knee circumference, and knee flexion range of motion. The Hyperice X was applied to the knee utilizing the contrast setting for a total of 18 minutes with three six-minute cycles, each consisting of three minutes of heat therapy and three minutes of cold therapy. The contrast therapy was applied at the initiation of the physical therapy session and all subjective and objective measures were repeated immediately post contrast treatment.

Results

The VAS scores significantly improved following the treatment session with the mean score pretreatment of 2.59 and following the treatment of 1.68. Knee circumference improved for mid patella and 5 cm below mid patella, but no significant improvement was noted at the 5 cm above the patella region. Knee flexion improved from 130 degrees

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pre-treatment to 134 degrees post treatment. Knee extension improved from 2.72 degrees of hyperextension to 3.44 degrees, both of which were statistically significant($p<.001$).

Conclusion

Contrast therapy utilizing the Hyperice X device demonstrated effectiveness in affecting pain reduction, swelling, and knee ROM. A commercially available device providing contrast therapy, may enhance outcomes in athletes after even a single treatment. In addition, the device was found to be easy to use, clinically practical, and demonstrated very high subjective patient satisfaction.

Level of Evidence

Level 3

BACKGROUND

Contrast therapy consists of alternating thermotherapy and cryotherapy applied repeatedly during a treatment session to assist in the management of acute, subacute, and chronic musculoskeletal conditions. Most commonly, this treatment intervention is performed by either the use of a hot and cold whirlpool or by applying hot and cold packs. Contrast therapy has been utilized for several decades with good to excellent subjective and objective results reported.[1–8] This therapeutic approach has been advocated for patients with swelling (acute to chronic), pain, and loss of motion. In addition, contrast therapy has been utilized effectively for recovery post exercise and sport participation.[1–8]

Numerous studies have demonstrated excellent clinical effects with the performance of contrast therapy.[1–3,9–11] Greenhalgh et al.[3] reported in a meta-analysis and systematic review utilizing contrast therapy in the management of both soft tissue injury and post exercise recovery beneficial effects for subjective measures such as fatigue, muscle soreness, and enhanced effects related to optimal recovery. Another systematic review of 23 peer reviewed articles by Higgins et al.[12] determined that contrast water therapy benefits recovery via effects on perceived fatigue following participation in team sports. Weerasekara et al.[8] prospectively studied the effect of contrast therapy on grade I and II lateral ankle sprains. The investigators reported the use of contrast therapy as an effective treatment modality for reduction of pain, improving ROM, and reducing swelling during the transition from acute to chronic management.

Although numerous studies have demonstrated a positive effect of contrast therapy,[1–7,9–11,13] in the authors opinion this intervention is under-utilized due to difficulty in application and the time required to set up the treatment for use. Contrast therapy utilizing warm and cold-water whirlpools or hot packs and ice packs repeatedly in various timed alternations during the treatment session is both equipment and labor intensive. The researchers postulated that if the application of contrast therapy was simplified, such as utilizing one device with the ability to regulate both heat and cold automatically, this treatment approach could be employed with greater ease. To this end, a new device has been developed called the HyperIce X (HyperIce Co. Newport Beach, CA) which allows the clinician to utilize a single device and one treatment sleeve able to produce heat up to 115 degrees and cold to 35 degrees in alternating cycles that can be easily controlled by the clinician.

The purpose of this study was to determine the efficacy of a single treatment with the Hyperice X system in reducing knee joint pain, swelling and stiffness in active patients and young injured athletes. A secondary purpose was to measure patient satisfaction with the use of the device.

METHODS

SUBJECT RECRUITMENT

Fifty subjects with a mean age of 22.2 +/- 4.9 yrs (ranging from 17 to 45 yrs of age) were recruited into the study. Subjects were recruited into one of two centers: a university athletic training room or an outpatient sports medicine rehabilitation center. Subjects presented with various types of knee pain, both non-operative and operative, secondary to ligamentous, tendinous, cartilage, muscle, and/or meniscus pathology. All subjects included in the study met the inclusion criteria.

Inclusion criteria for the investigation were either male or female athletes 18 years of age or older who were experiencing knee pain, swelling and/or stiffness. For the purposes of this study an athlete was defined as "a physically active individual who span the spectrum across age, race/ethnicity, illness or injury condition, and level of ability/disability," by the Sports Physical Therapy Description of Specialty Practice.[14] The subjects were in various stages of the rehabilitation with six in the acute stage, 24 in subacute and 20 in the chronic stage. Exclusion criteria included: an immediate post-operative condition (within three weeks of injury), open wounds or incisions, inability in the judgement of the investigators to be able to complete the study and/or unwillingness to participate.

OUTCOME MEASUREMENTS

Two specific subjective and two objective outcome measurements were utilized for the study. Subjective measures included pain reporting using a visual analog scale (VAS) and patient satisfaction. Patient satisfaction was evaluated by the researcher asking them how satisfied they were, with patients reporting verbally using a scale from 0 to 10 (with 0 being completely unsatisfied, and 10 completely satisfied). The objective outcomes included circumferential measurements taken at three anatomic landmarks, and active range of motion (ROM) of knee flexion and extension assessed using a standard goniometer.

STUDY DESIGN

The study was reviewed and approved by the Institutional Review Board and all subjects consented to participate in the study.

Once admitted to the study, subjects were evaluated for baseline pain using the VAS, as well as swelling, and stiffness. Swelling was measured using girth measurements for circumference (cm) taken around the knee at the level of mid-patella, 5cm above the border of the patella, and 5cm below the border of the patella. Stiffness was assessed via measurements of active knee flexion and extension range of motion in supine. The baseline measurements were taken by the same clinician at each of the two facilities to ensure reproducibility.

After baseline measurements were collected, the Hyperice X was applied to the knee utilizing the contrast setting, at the beginning of the therapy session. This ran for a total of 18 minutes with three six-minute cycles, each consisting of three minutes heat therapy and three minutes of cold therapy. Immediately post contrast treatment, all objective and subjective assessments were repeated. If a patient became uncomfortable during the 18 minutes that the Hyperice X was on the knee and requested that it be removed, the Hyperice X was removed, and the participant was withdrawn from the study. During this study no subjects prematurely terminated treatment.

STATISTICAL ANALYSIS

Descriptive statistics including mean, and range were calculated for all continuous variables. Pre- and post-session data were compared using the student t test. Significance was set at $p<0.05$.

RESULTS

The subjects participating in the study consisted of 34 males and 16 females. The mean BMI for males was 25.1 +/- 3.4 and for females 22.4 +/- 2.02. The sports and position played at time of injury are detailed in Table 1. The specific type of injury, stage of the rehabilitation, involved extremity, and whether the dominant or non-dominant side was involved are listed in Table 2.

The VAS scores significantly improved following the treatment session with the mean reported score pretreatment of 2.59 and following the treatment the score reduced to 1.68 ($p<0.05$). Knee circumference decreased for mid patella and 5 cm below mid patella($p<0.05$) but no significant improvement was noted at the 5 cm above the patella region. Knee range of motion improved for both knee flexion and extension. Knee flexion improved from 130 degrees (+/- 18.91) pre-treatment to 134 degrees (+/- 18.08) post treatment. Knee extension improved from 2.72 degrees (+/- 3.37) of hyperextension to 3.44 degrees (+/- 3.30), ($p<0.05$). Lastly, subjects reported scored their satisfaction with the treatment device to be very high, with a score of 8.8 +/- 1.6 out of a maximum score of 10. Pre and post treatment data can be found in Table 3. During the study all subjects reported no discomfort, pain, or increase in symptoms during the treatment.

DISCUSSION

This is the first study to utilize a commercially available single physical agent unit that provides contrasting heat and cold treatment, managed through an application on a phone or other electronic device. The advantages of such a device include efficiency, portability of treatment, and flexibility often required in the sports medicine environment. The results of this study are significant in several areas.

Each subject wore the device for the entire time of the treatment protocol, with no early termination requested. Overall, the authors believe that contrast therapy, as investigated in this study, produces an alternating pumping action of vasodilation followed by vasoconstriction, thus resulting in a flushing mechanism of fluid from the area. This has been anecdotally reported by clinicians for years and is one of the primary purposes for the use of contrast treatments. The authors of this study believe this is especially beneficial in cases of chronic swelling and possibly subacute conditions. The authors believe in the acute condition, ice, compression, and elevation would be most beneficial.

The subject's subjective outcome of the VAS scores significantly improved following a single application with the mean score difference of 0.81. The effect on VAS pain score demonstrates the influence on neural transmission that is consistent with both cryo and thermal modalities. Subjects reported a statically significant reduction in their knee pain with a mean difference of -0.91 ($p<.001$). While this difference is statistically significant, it may not be considered clinically significant dependent of the patient population and diagnoses. Minimum clinically important difference (MCID) is variable based on diagnosis, therefor because this study was performed using a variety of diagnoses the MCID is not established. Anecdotally, subjects often reported following the application of the contrast treatment that their knee "felt good or felt better" following the application of the contrast treatment. The authors were encouraged by this response from almost all subjects, as it has been stated that the number one reason patients seek musculoskeletal treatment is because of a pain and if contrast therapy can reduce a patient's complaint of pain, their dysfunction may be easier to address.[13]

Following the application of the device, there were statistically significant improvements in circumferential measurements at the mid patella mark and 5 cm below that point, which represents the region of the joint capsule reflecting a joint effusion reduction. Circumferential measurements did not significantly improve at 5cm above the mid patella. This result would be expected based on the potential influence of any modality on joint swelling. In addition to vascular pumping, the improvement in circumferential measures could be due to a decrease in both interstitial as well as intracapsular swelling in the knee joint, based on the patient's case, following utilization of the device. The knee capsule may not extend to 5CM above the patella; therefore no effect is expected.

Statistically significant improvement in knee flexion was seen following the application of contrast treatment. Knee flexion improved with a mean difference of 4.36 degrees ($p<.001$). Again, this improvement may be due to a decrease in both interstitial and intracapsular swelling as noted

Table 1. Sports and position for men and women in the study.

Gender	Sport	Position	# Athletes
Female	Basketball	Center	1
		Guard	1
	Soccer	Center Back	1
		Forward	1
		Goalkeeper	1
		Midfield	2
	Soccer College	Defender	1
	Track and Field	Jumper	3
	Volleyball	Middle	1
		Middle Blocker	1
		Outside	1
	Women's Lacrosse	Attack	1
		Midfield	1
Male	Ballet Professional	Dancer	1
	Baseball	SS	1
	Baseball College	Pitcher	1
	Baseball Professional	Pitcher	2
	Basketball	Forward	3
		Guard	6
		Point Guard	1
	Basketball Professional	Guard	1
	College Student	Rec Soccer	1
	Football	DB4	1
		Offensive Line	1
		Punter	1
		Quarterback	1
		RB	1
		TE	3
		WR	1
	Football Professional	Quarterback	1
	Golf	Golf	1
	Physician	Rec Soccer	1
	Real Estate	Rec Athlete	1
		Rec Skier	1
	Teacher	Rec Athlete	1
	Tennis HS	Tennis	1
	Track and Field	Track	1

above. At the conclusion of each treatment, subjects were asked to subjectively report their perceived knee tightness. They reported less posterior knee tightness after the contrast treatment, which may suggest the reduction of knee swelling in the posterior compartment of the knee. Knee extension following the contrast treatment improved only slightly by 0.71 degrees ($p<.001$). This could be attributed to a decrease in joint swelling, the knee subjectively feeling better, patient comfort, or patient relaxation

Finally, the subjects reported their satisfaction with the use of the during the treatment session. The overall satisfaction score following the session was 8.8 ± 1.6, with a range between 3-10. The most frequent scores given were either a 9 or 10, illustrating an overall high subject-reported satisfaction using the device

Table 2. Injuries per gender and dominance side.

Gender	Injury	Side	Dominance	# Athletes & Stage of Recovery
Female	ACL Tear	Left	Non-dominant	3 Chronic
		Right	Dominant	1 Chronic
	ACL/MCL tear	Left	Non-dominant	1 Subacute
	ACL/PTG	Right	Dominant	1 Subacute
	ACLR	Left	Non-dominant	1 Subacute
	Acute Knee Pain	Left	Non-dominant	2 Acute
		Right	Dominant	1 Acute
	Chronic knee pain	Right	Dominant	1 Chronic
	MPFL and lateral OCD	Right	Dominant	1 Subacute
	Patellar Tendinitis/tendinopathy	Left	Non-dominant	1 Subacute
		Right	Dominant	1 Subacute
	Patellar tendon debridement	Left	Non-dominant	1 Subacute
	PCL Tear	Right	Dominant	1 Subacute
Male	Achilles Repair	Right	Dominant	1 Chronic
	ACL	Right	Dominant	1 Subacute
	ACL Recon	Left	Non-dominant	1 Subacute
	ACL Tear	Left	Non-dominant	1 Subacute
	ACL, B Meniscus, MCL, OCD	Right	Non-dominant	1 Chronic
	ACL, Partial MCL, Partial Meniscus	Right	Dominant	1 Subacute
	ACL/PTG	Left	Non-dominant	1 Chronic
		Right	Dominant	3 Chronic
	ACL/QT	Right	Dominant	1 Subacute
	ACLR	Left	Non-dominant	1 Chronic
	Acute Knee Pain	Left	Non-dominant	1 Acute
	Chronic knee pain	Left	Non-dominant	2 Chronic
	Knee Pain	Right	Dominant	1Acute
	MCL Repair	Left	Non-dominant	1 Subacute
	MCL Sprain	Left	Non-dominant	1Acute
	MCL Sprain	Right	Dominant	1 Subacute
	Meniscus Post-op	Left	Dominant	2 Subacute
			Non-dominant	1 Subacute
		Right	Dominant	1 Chronic
	MPFL	Right	Dominant	1 Chronic
	OCD	Right	Dominant	1 Chronic
	Patellar Tendinitis/tendinopathy	Left	Dominant	1 Chronic
		Right	Dominant	2 Chronic
			Non-dominant	1Subacute
	PF Pain	Left	Non-dominant	1 Subacute
		Right	Non-dominant	1Subacute
	UCL Reconstruction*	Left	Dominant	1 Subacute
	UCL Repair*	Left	Dominant	1 Subacute
		Right	Dominant	1Subacute

*ACL – Anterior Cruciate Ligament, MCL – medial collateral ligament, PTG – patellar tendon graft, ACLR – anterior cruciate ligament reconstruction, MPFL – medial patellofemoral ligament, OCD – osteochondral defect, PCL – posterior collateral ligament, QT – quad tendon, PF – patellofemoral, UCL – ulnar collateral ligament, *treating diagnosis with complaint of knee pain secondary*

Table 3. Pre and post treatment measurements.

Variable	Pre (Mean ± SD)	Post (Mean ± SD)	Mean Difference post-pre	CI (95%)	p-values	Effect size (Cohen for repeated)
Visual Analog Scale	2.59 ± 2.18	1.68 ± 1.74	-0.91	(-1.22, -0.60)	P<.001	-0.87
Knee Extension AROM (degrees)	2.72 ± 3.37	3.44 ± 3.30	0.72	(0.33, 1.11)	P<.001	0.61
Knee Flexion AROM (degrees)	130.04 ±18.91	134.40 ± 18.08	4.36	(3.33, 5.39)	P<.001	2.28
Knee Circumference (5cm superior patella) (cm)	40.98 ± 4.02	40.81 ± 3.91	-0.17	(-0.43, 0.89)	P=0.19	-0.18
Knee Circumference (Mid-patella) (cm)	38.57 ± 3.50	38.11 ± 3.28	-0.46	(-0.25, -0.68)	P<.001	-0.53
Knee Circumference (5cm inferior patella)	35.18 ± 3.08	34.71 ± 3.12	-0.47	(-0.69, -0.24)	P<.001	-0.52
Patient Satisfaction Post Session		8.8 ± 1.6				

G-power: n=34 (alpha=0.05; beta=0.20 / power = .8; effect size = 0.5)
AROM: Active range of motion; cm: centimeters

LIMITATIONS

The investigators of this study feel there were several limitations: First, there was no control group to compare the contrast treatment to. This would have enhanced the results and would have been an important comparison of treatment effects. Second, this study utilized an active population, either collegiate or recreational athletes rendering the results somewhat specific to active individuals. Furthermore, subjects were not separated into different stages of the rehabilitation – which could provide additional insights into effectiveness of contrast treatment over time. In addition, although the results were found to be significant there could exist a margin of measurement error regarding circumference measurements and goniometric measurement. Lastly, there were no follow up assessments performed to determine the lasting effects of the intervention. Further studies need to be performed to determine the effects on the general population and older patients, effects on various stages of recovery, and specific pathologies with the Hyperice X contrast device. In addition, studies to investigate the effects of longer treatment sessions, repeat treatment sessions, and effects over time are needed to enhance the clinical significance of the use of this device and others like it.

CONCLUSIONS

The results of this investigation indicate that a commercially available contrast therapy device was able to provide statistically significant improvement in several key treatment areas, including reductions in pain and swelling, and improvement in knee ROM after only a single treatment. These improvements in objective outcomes show promise for clinical applicability and may be important in the treatment of knee swelling in an athletic population. In addition, the subjects included in this study expressed a high degree of overall satisfaction with the treatment. The researchers also found the device easy to use and clinically practical.

COI

Kevin Wilk is on Medical Advisory Board for Hyperice, no other investigators/authors disclose a potential conflict of interest.

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