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Cryo plus Ultrasound Therapy, a Novel Rehabilitative Approach for Football Players with Acute Lateral Ankle Injury Sprain: A Pilot Randomized Controlled Trial

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Abstract

Background: Acute lateral ankle sprains are common injuries among athletes, but the optimal treatment strategies in elite athletes are still debated. This proof-of-concept study aimed to assess the impact of cryo-ultrasound therapy on the short-term recovery of football players with acute lateral ankle sprains. Methods: Semi-professional football players with grade I or II lateral ankle sprains were randomly assigned to the experimental group (receiving cryo-ultrasound therapy combined with conventional physical therapy) or control group (sham cryo-ultrasound therapy combined with conventional physical therapy). Pain intensity and physical functioning were assessed by the Numeric Rating Scale (NRS) and Foot and Ankle Disability Index (FADI) at baseline (T0) at the end of treatment (T1), after one month (T2), and two months after treatment (T3). Results: After the study intervention, significant between groups differences were reported in terms of pain relief (NRS: 4.08 ± 1.29 vs. 5.87 ± 1.19; p = 0.003) and physical function (FADI: 50.9 ± 10.3 vs. 38.3 ± 11.5; p = 0.021). However, no significant between group differences were reported at T2 and T3. No adverse effects were reported. Conclusions: Cryo-ultrasound therapy combined with conventional physical therapy can accelerate recovery and early return to sport in elite football players with acute lateral ankle sprains. While this study contributes valuable insights into the potential benefits of cryo-ultrasound therapy, further investigations with a longer follow-up are needed to validate and optimize the application of physical agent modalities in the management of ankle injuries.

1. Introduction

Ankle injuries are highly prevalent among professional and amateur sports, with the most typical mechanism of injury involving the combination of plantar flexion with foot inversion [1]. This injury usually shows lateral ligaments of the ankle impairments, with an incomplete tear of one or more ligaments, which could be treated conservatively; indeed, after acute ankle sprains, initial immobilization using a soft splint resulted in faster recovery than simple tubular bandage compression [2].

In this scenario, a short-term immobilization with functional physiotherapy is preferable to 2/3 weeks conventional therapy with plaster [3]. Albeit, there is substantial evidence on the management of ankle injuries [4–9], but there is a disagreement regarding the best therapy management for acute ligament injuries in elite athletes, particularly during COVID-19 era [10–13].

However, nonsurgical therapies can be prescribed for most acute grade I–III lateral ligament sprains with good to excellent outcomes; in detail, physical therapy and several pharmacological treatments and physical agent modalities can be utilized to enhance pain relief and tissue healing, including: diathermy, laser therapy, ultrasound therapy, and other forms of electrical therapies [14–16].

In 2012, van den Bekerom et al. [17] suggested that the possible effects of ultrasound therapy seem to be mostly mild and there is the possibly of partial clinical implication, particularly in the short term of the rehabilitation program after these injuries; however, the evidence was insufficient to define an adequate dosage of ultrasound therapy that would be beneficial. On the other hand, ultrasound therapy has been described as a helpful treatment in relieving pain in sports injuries, acting as an edema regulator, presumably by increasing pain thresholds, collagen flexibility, reducing edema and, consequently, inflammation and joint stiffness [18]. Considering the current evidence, cryotherapy appears to be effective in reducing pain, although compared to other rehabilitative approaches, the effectiveness of cryotherapy is still considered as controversial [19,20]. The real effect of cryotherapy on the most frequently treated acute injuries, such as joint sprains or soft tissue injuries, has not been completely explicated [21]. Furthermore, the poor methodology of the current evidence is of concern, so further research is needed to produce proper guidelines of cryotherapy approach and usage, focusing on the development of modalities, durations, and frequencies of ice treatment for dealing with the injury [22–24]. In fact, Kwiecien et al. stated that cryotherapy-induced metabolism decreases in inflammation and tissue damage have been proved in an in vivo muscle injury model; nonetheless, analogous evidence in humans is absent. This lack of evidence is prospective due to the insufficient length of application of conventional cryotherapy approach. The conventional application of cryotherapy must be repeated to address this concern [22].

Newly, literature engagement has been raised on the role of cryo plus ultrasound therapy, a physical agent modality that combines cryotherapy (cold therapy) with therapeutic ultrasound [25]. This treatment has been used for soft tissue injuries and inflammatory conditions, mainly in sports medicine and rehabilitation [26]. In this context, the combination of cold and ultrasound, using a single device, might create a synergistic effect, providing both anti-inflammatory and tissue-repairing benefits [26]. Despite these considerations, there is nevertheless a considerable gap of knowledge on the therapeutic effects of cryo plus ultrasound therapy in patients with acute ankle sprain. Furthermore, to date, no previous trial characterized the role of a specific cryo plus ultrasound therapy by a single device in the conventional rehabilitation of elite athletes with acute ankle sprain. Therefore, the purpose of this pilot randomized controlled trial was to assess the impact of cryo plus ultrasound therapy in the short-term recovery of football players affected by acute lateral ankle sprain.

2. Materials and Methods

2.1. Participants

This trial was evaluated and registered by the local ethics committee (Comitato Etico Territoriale Regione Calabria) providing the following code: 115/2022, in respect of the Declaration of Helsinki and following the ethical guidelines of the responsible legislative institute. Athletes were educated about the aim of the pilot trial and provided informed consent to collect clinical information for scientific assessments and purposes. All rights of the enrolled subjects in the present study were protected. All authors and research participants were educated in caring about the privacy of the subjects involved. Inclusion criteria were: (a) adult male; (b) semi-professional football players; (c) I–II grade lateral ankle sprain injury; (d) no persistent instability phenomena or chronic sprains; (e) acute injury (within 2 weeks from trauma); (f) no evidence of bone edema or skin disorder, once the area of intense pain in motion was delimited, the lack of neurological disturbances was investigated and assessed.

Exclusion criteria were: (a) history of recurrent dislocation of the ankle or hyperlaxity of any joint; (b) severe rheumatic diseases and/or collagen diseases; (c) athletes who have received any form of local physical therapy and NSAIDs within the last 2 months prior to injury; (d) athletes who admit to using steroids; (e) any contraindication and/or limitation to the use of a physical agent modality (implantable electrophysiological devices, active neoplasms).

Then, all the athletes included in this pilot trial were randomly allocated with a 1:1 ratio in an experimental group and control group. Randomization was performed by an author not involved in this step of the process of the study using random blocks.

2.2. Intervention

Both groups followed the same rehabilitation program in the first week, while the patients were treated with the experimental or sham intervention during the following 2 weeks. During the first week, the approach consisted of a synthetic splinting system for joint immobilization, Canadian crutches for weight-bearing ease, draining massage performed by a physiotherapist with progressive proprioceptive exercises.

After the first week, participants of the experimental group underwent a combination of cryotherapy and ultrasound therapy treatment. The treatment was performed by an expert physiotherapist with a single Cryosound 1.16 device (ELCAP—Giarre CT, Italy) for both treatment groups [6].This device simultaneously delivers cryotherapy and therapeutic ultrasound with the same applicator, not allowing the patient (the blind component of the study) to recognize which type of therapy he was undergoing.

Figure 1. Cryo-ultrasound therapy device

The experimental group was subjected to continuous application of cryo-ultrasound, with a temperature of −2 ◦C and a power of 1.8 watt/cm2 , as illustrated in Figure 1. In the control group, a sham treatment was provided without the administration of ultrasound therapy and with the use of only the perceptible sensation of cold, but not at the therapeutic level of cryotherapy. All patients cannot recognize the dummy therapy because the device looks the same as the active one. A 40 min session was performed for both groups, the first 20 min dedicated to rehabilitation recovery of articular function and proprioceptive exercises and the remaining 20 min for the execution of cryo-ultrasound therapy for the active or sham group.

For conventional physical therapy, stretching exercises were conducted in the early phase with closed-chain ankle motions and unloaded dorsiflexion stretching approaches progressing to standing calf stretch and global joint stretching in open-chain [11]. In parallel, progressive strengthening exercises were performed after pre-injury ROM recovery, starting with isometric exercises in both the frontal and sagittal planes. Next, the player moved to isotonic resistance exercises using weights, bands, or therapist manual resistance for all planes pain-tolerated motions [27]. Finally, in the initial stages, PNF exercises started with intrinsic movement of the foot (extension of the toes with plantar flexion of the ankle/flexion of the fingers with dorsiflexion of the ankle) and trainings implemented on a surface of different consistencies, a plank wedge, or a Bosu [28]. Firstly, the subject should start with a wedge plank in an anteroposterior direction; lastly, with greater pain control, a seated Biomechanical Ankle Platform System (BAPS) was utilized for all planned exercises.

2.3. Outcome Measures

Pain intensity was considered as the primary outcome measure with a pain numeric rating scale (NRS); considered by any functional activity or movement of the injured ankle. The NRS is an 11-point numerical score from 0 demonstrating "no discomfort" to 10 expressing the "worst pain ever felt".

Secondary outcome measures were the Foot and Ankle Disability index (FADI), utilized as a degree of functional limitation related with foot and ankle disorders; involving a 26-item sub-score of daily living and pain; each element has a score from 0 (unable to do) to 4 (no difficulty at all). The total possible score is 104 points and a lower score indicates a higher value of functional limitation. Finally, we evaluated quality of life through EuroQol5D (EQ-5D) index. All patients underwent clinical follow-up at the end of treatment (T1), after 1 month (T2), and 2 months after the end of treatment (T3)

2.4. Statistical Analysis

Statistical analysis was performed using JASP Statistical Package (1.16 Amsterdam, The Netherlands). Data were verified for normal distribution according to Shapiro–Wilk test. Homogeneity of variance analysis was assessed via Leven's test. Categorical or dichotomous variables were summarized with frequencies. Continuous data were presented with means and standard deviations. Effect sizes were presented through Cohen d (95% Confidence interval), all outcome data were calculated for within group and between group differences from different time points. Effect sizes were interpreted as minor <0.5; adequate between 0.5 and 0.8; and large, >0.8. For each test, statistical analyses were 2-tailed and a p-value cut-off set at <0.05 was considered significant. The G-Power statistics module from JASP software was used to ensure the assessment of the appropriate sample size. Assuming an alpha level of 0.05 and 80% power, through an effect size of 0.40, with a repeated measure analysis of variance between group interactions, an appropriate sample size was set at 23. This was enlarged to 26 (13 participants per arm) regarding a potential 10% dropping out assumption, and an equal group distribution of subjects included. This study was evaluated and approved by the local ethics committee (Comitato Etico Territoriale Regione Calabria) providing the following code: 115/2022.

3. Results

In total, 25 players who met the trial eligibility and who observed the follow-up were evaluated, as depicted in Table 1. Twelve patients were enrolled in the control group, whereas thirteen participants were included in the experimental group. The mean age of the players enrolled in the pilot trial was 22.8 ± 12.62 years. At T0, the groups did not report any demographic and morphometric differences.

Characteristic	Group Exp (n = 13)	Group Cnt (n = 12)	*p*-Value
Age (y), mean ± SD (range)	22.5 ± 12.4 (18 to 41)	23.1 ± 11.5 (21 to 38)	0.114
Weight (kg)	75.1 ± 13 (47 to 88)	77 ± 14 (50 to 92)	0.085
Body mass index, mean ± SD	23.2 ± 4 (19 to 29)	22.9 ± 5 (18 to 30)	0.102
NRS (0–10), mean ± SD	7.69 ± 2.19	7.79 ± 1.19	0.214
EQ-5D-3L Index, mean ± SD	0.5 ± 0.3	0.6 ± 0.2	0.112
FADI (0–104), mean ± SD	32.9 ± 10.5	28.3 ± 10.6	0.079

Abbreviations: Cnt, Control Group; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; Exp, Experimental group; FADI, Foot and Ankle Disability Index; NRS, Numerical Rating Scale; SD, standard deviation.

Table 1. Demographic and morphometric characteristics with baseline evaluations of self-reported scales.

A baseline subject assessment reported that both groups had noticeable intensities of pain, with no significant differences between the groups. Nonetheless, starting from T1 and during the treatment plant, the athletes who were enrolled in the experimental group had a significantly larger pain decrease than the control group; however, at T3, similar results were reported in both groups. In parallel, the FADI results showed comparable levels of progress over time for both study groups. Despite these results, patients who received the active cryo plus ultrasound device management displayed significant enhancement in control subjects at T1, but similar results at T3 (Table 2).

Table 2. Within group differences in the outcome measures for active cryo-ultrasound therapy and control groups.

		T0	T1	ΔT0-T1		T2	ΔT1-T2		T3	ΔT2-T3	
				p	ES		*p*	ES		*p*	ES
NRS (0–10)	*active*	7.69 ± 2.19	4.08 ± 1.29	0.006	−0.9	3.29 ± 1.05	0.041	−0.3	2.78 ± 0.91	0.083	−0.5
	sham	7.79 ± 1.19	5.87 ± 1.19	0.009	−0.6	4.06 ± 1.37	0.052	−0.4	2.86 ± 1.37	0.042	−0.5
FADI (0–104)	*active*	32.9 ± 10.5	50.9 ± 10.3	0.031	0.7	79.9 ± 8.5	0.005	0.7	96.6 ± 7.6	0.012	0.6
	sham	28.3 ± 10.6	38.3 ± 11.5	0.027	0.5	76.6 ± 11.2	0.009	0.5	94.5 ± 7.1	0.039	0.6
EQ-5D-3L	*active*	0.5 ± 0.3	0.6 ± 0.2	0.106	0.1	0.7 ± 0.3	0.093	0.0	0.7 ± 0.3	0.0	−0.7
	sham	0.6 ± 0.2	0.7 ± 0.3	0.124	0.1	0.7 ± 0.2	0.082	0.0	0.7 ± 0.2	0.0	−0.7

All data are expressed as means ± standard deviations. Abbreviations: ES, Effect size; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; FADI, Foot and Ankle Disability Index; NRS, Numerical Rating Scale; SD, standard deviation.

In the light of these paired results, we evaluated the differences between the groups at each time point, as shown in the Table 3.

Table 3. Between group differences in the outcome measures for active cryo-ultrasound therapy and control groups

		T0		T1		T2		T3		ANOVA-RM
		p-Value	ES	*p*-Value	ES	*p*-Value	ES	*p*-Value	ES	*p*-Value
NRS	*active* / *sham*	0.744	−0.06	0.003	−0.69	0.212	−0.65	0.534	−0.06	0.002
FADI	*active* / *sham*	0.2	0.20	0.021	0.57	0.345	0.23	0.386	0.21	0.039
EQ-5D-3L Index	*active* / *sham*	0.106	0.11	0.127	0.21	0.242	0.13	0.342	0.09	0.128

Abbreviations: ES, Effect size; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level Version; FADI, Foot and Ankle Disability Index; NRS, Numerical Rating Scale; SD, standard deviation.

Moreover, we reported the repeated measures analysis as a cumulative evaluation also at the follow-up (for further details, see Figure 2).

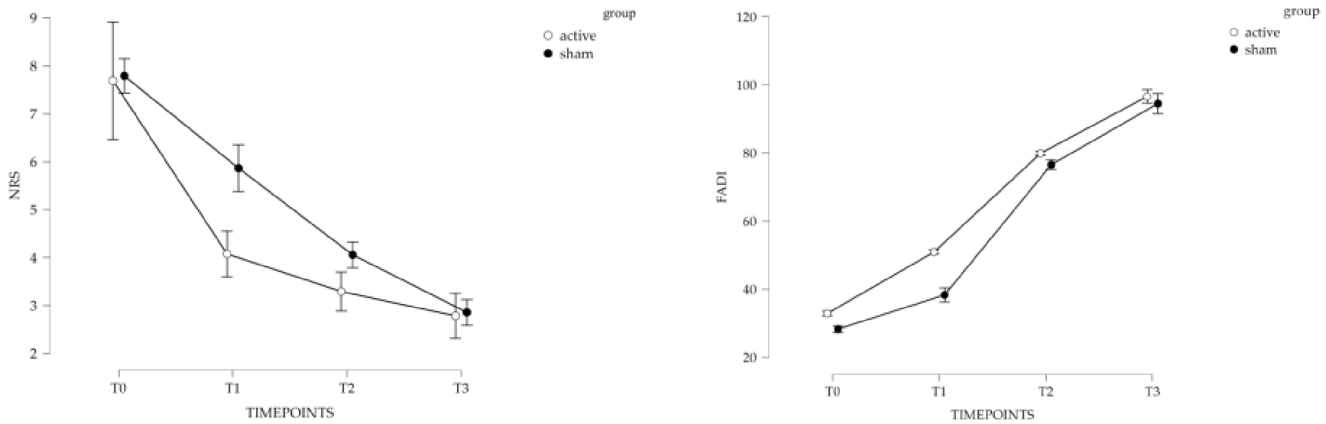

Figure 2. Marginal means plot for NRS and FADI assessment.

4. Discussion

This pilot randomized controlled trial aimed to evaluate the short- and long-term effects of cryo plus ultrasound therapy, using a single device, with conventional physical therapy versus conventional physical therapy alone in football players with acute and subacute I–II grade ankle sprain.

At the end of the treatment (T1), active cryo plus ultrasound therapy, in addition to the group treated with conventional physical therapy, allowed the players to obtain high pain relief (NRS, active group: 4.08 ± 1.29 compared to the sham group: 5.87 ± 1.19) and an increase in FADI scale score (active group: 50.9 ± 10.3 vs. sham group: 38.3 ± 11.5); however, similar results were observed at two weeks (T2) and four weeks (T3) of follow-up in both groups, without any side effects. Conversely, these results legitimize the effectiveness of conventional physiotherapy in the medium term; nonetheless, in the short term, they demonstrated an accelerated recovery and consequent early RTS for the group treated with the synergistic use of cryotherapy and ultrasound therapy.

Unfortunately, there are common mythoi and fallacies in ankle sprain management; these embrace numerous and unnecessary imaging, inapt non-weight bearing, unwarranted immobilization, delayed functional recovery, and inadequate rehabilitative approaches.

The application of an evidence-based tailored program that embraces the individual characteristics of the sportsperson could be useful and should be recommended [11].

Logan et al. [29] reported that ultrasound therapy could provide therapeutic effects in the control of pain symptoms especially in sports-related disorders, in edema management, as well as in the reduction in stiffness and functional improvement of joint ROM, plausibly raising the pain threshold, the microstructural flexibility provided by collagen fibers, resolving the edematous framework, as well as the cytokine pattern underlying the inflammation, up to muscle and joint spasms [29]. In 2011, a systematic review on acute ankle sprains concluded that UST was no more effective than a placebo in treating pain and edema, without providing details on the techniques used for measuring UST parameters [30,31].

Doherty et al. [32] suggested that there is a lack of evidence to examine the efficacy of UST in treating acute ankle sprains; the need for rigorous RCTs to demonstrate efficacy has been emphasized. In this scenario, Daniel et al. [33] concluded that the association of UST with taping and PNF training plus tape applications was most advantageous in the treatment and rehabilitation of high ankle sprain injury; indeed, the author suggested that combined effect functional training with UST could be explored by future research.

In fact, Kinkade's data reported that ice applications and heat packs had matching results [34]; while Costello et al. [35] established that a whole-body cryotherapy (−110 degrees C) administration provided prompt pain relief and, after 15 min, also reduced muscle tone. Lastly, ice could ensure an analgesic result, which might also facilitate therapeutic exercise in early rehabilitative phase [10]. In this scenario, it can be stated that cryotherapy, applied by a specific device, has an immediate and profound analgesic effect on severe nociceptive pain and accelerates the tissue healing process by reflex vasodilatation followed by vasoconstriction [36,37].

Dehghan et al. [38,39] recommended further studies that could measure the combined effects of different rehabilitative approaches including cryo and thermo-therapy, PNF, acupuncture, etc., on the control of pain. Indeed, there is no sufficient evidence that applying ice alone might decrease pain and swelling, as well as enhancing functioning in people with a I–II grade acute ankle sprain [40,41]. Nevertheless, cryotherapy for 3 to 7 days is habitually utilized to decrease pain, diminish swelling and bleeding, reduce the effects of vasoconstriction; furthermore, the administration of spray or ice packs with a 20 min protocol every two hours is commonly considered to be useful [42]. Additionally, it is often suggested that intermittent immersion cold therapy could be supportive for early pain decrease [11]. The innovative element of this pilot randomized controlled trial is instead the usage of a single device for the delivery of the physical agent, without providing an empirical application but guaranteeing the use of an instrumental combination with the same applicator for cryo and UTS [11].

In an injured sportsperson, appropriate timing and safe RTS or competition is the estimated outcome of the rehabilitative approach [43,44]. In this scenario, the sports doctor would finally have to decide on the athlete's readiness to RTS, following a complex procedure with controversial indication from various bases [45–48]. On the other hand, getting feedback from rehabilitation team members is imperative, as many of the crucial outcomes might not be assessed or supervised in appropriate settings [49]. The proper RTS timing is often based on the severity of the injury, considering that a common mild ankle sprain might take a 4 week recovery plan and a more deep syndesmotic damage takes 8 weeks for an adequate RTS [50,51]. Since several professional players (particularly in contact sports such as basketball, football and soccer) might often have suffered multiple ankle injuries, with a common joint instability, a safe and rapid approach can be of great help to sports medical personnel [14,52]. Clearly the athlete's tissue healing response may depend on key factors such as age, genetic patterns, player experience with pre-injury condition, and their following of the rehabilitation protocol [9,53–55].

4.1. Future Perspectives

Cryotherapy seemed to play an antalgic role in the immediate post-trauma period and also to accelerate recovery; this could suggest that the cryoultrasound approach partially contributes to pain reduction, but larger follow-ups will be needed, even if it will be difficult to objectify them by the acute nature of the disorder [26]. On the other hand, cryotherapy would seem to generate a cooling cone in the tissue through which the highpower ultrasound waves would pass, producing a deep thermal result, which is well tolerated and efficient in reducing painful symptomatology, developing a trophic effect [54], but larger samples with more stringent inclusion criteria will be needed.

4.2. Study Limitations

However, this proof-of-concept study is not without its limitations. First, one latent limitation is that the ending follow-up is quite undersized. Nonetheless, because ankle sprains are an acute and often self-limiting disorder, longer follow-up might make it difficult to attribute recovery to intervention alone, compromising both findings and conclusions.

Secondly, in this context, it is difficult to be aware of the actual return to play, sport, or tangible pre-injury performance. However, in the athlete's competitive context, the incompetence to run or jump, and therefore to train, is the most key feature to study, which is why we consider the FADI to be a truly reliable index for this purpose. Third, there is no assessment of a long-term follow-up. Lastly, both cryotherapy and ultrasound therapy, to the best of our knowledge, do not have an appropriate and recommended dosage for these patients, on the other hand this is the first study aiming to analyze the combined approach and to provide, as much as possible, the two physical agent modes using a single device.

5. Conclusions

In conclusion, this a pilot randomized controlled trial aimed at evaluating the impact of cryo plus ultrasound therapy, using a single device, on the short-term recovery of football players with acute lateral ankle sprains. Taking together our findings suggested that cryo plus ultrasound therapy can accelerate recovery and an early return to sport in elite athletes. Overall, this study contributes to the understanding of the potential benefits of cryo plus ultrasound therapy in the management of acute lateral ankle sprains of elite athletes. Further studies with longer follow-ups are needed to confirm these positive data and to explore and refine the use of physical agent modalities to optimize the recovery and return to sport of athletes with ankle injuries.

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Data Availability Statement: Data are not available due to ethical restrictions.

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Anna Tripi, physiotherapist, studies the management of three clinical cases with Cryo Sound technology in order to evaluate restitutio and recovery with this technology combined with functional exercise

Introduction

Let's analyze the three patients treated with the related clinical cases:

- Patient A: Male, age 56. Trauma from fall.

Performed on 11/09/23 MRI of the right knee which revealed a lesion of the medial component (vastus medialis) of the tendon of the quadriceps femoris.

The muscle ultrasound performed on 09/18/23 outlines the severity of the injury with "rupture of the quadriceps tendon at the muscle-tendon insertion with detachment of the patella tendon extending for 5.5 cm: modest amount of supra-patellar effusion". (Figure 1-2)

- Patient B: Female, age 64. Affected by osteoarthritis of the left knee.

MRI performed on 04/18/23 with "fair endoarticular effusion with fluid distention of the recess of the gastrocnemius-semimembranosus" (popliteal hollow cyst of the DM of approximately 5.9 cm). (Figure 3)

- Patient C: Male, age 62. Left biceps brachii muscle trauma.

Performed on 09/19/23 Muscle ultrasound showing injury and hematoma (see attachment). (Figure 4)

A therapeutic plan with Cryo Sound of 6 sessions (3-4 times a week) with 20 minute application combined with the relevant specific therapeutic exercise was implemented for each patient in order to evaluate:

- Pain reduction (Vas);
- Recovery of joint range of motion (ROMp);
- Active recruiting ability.

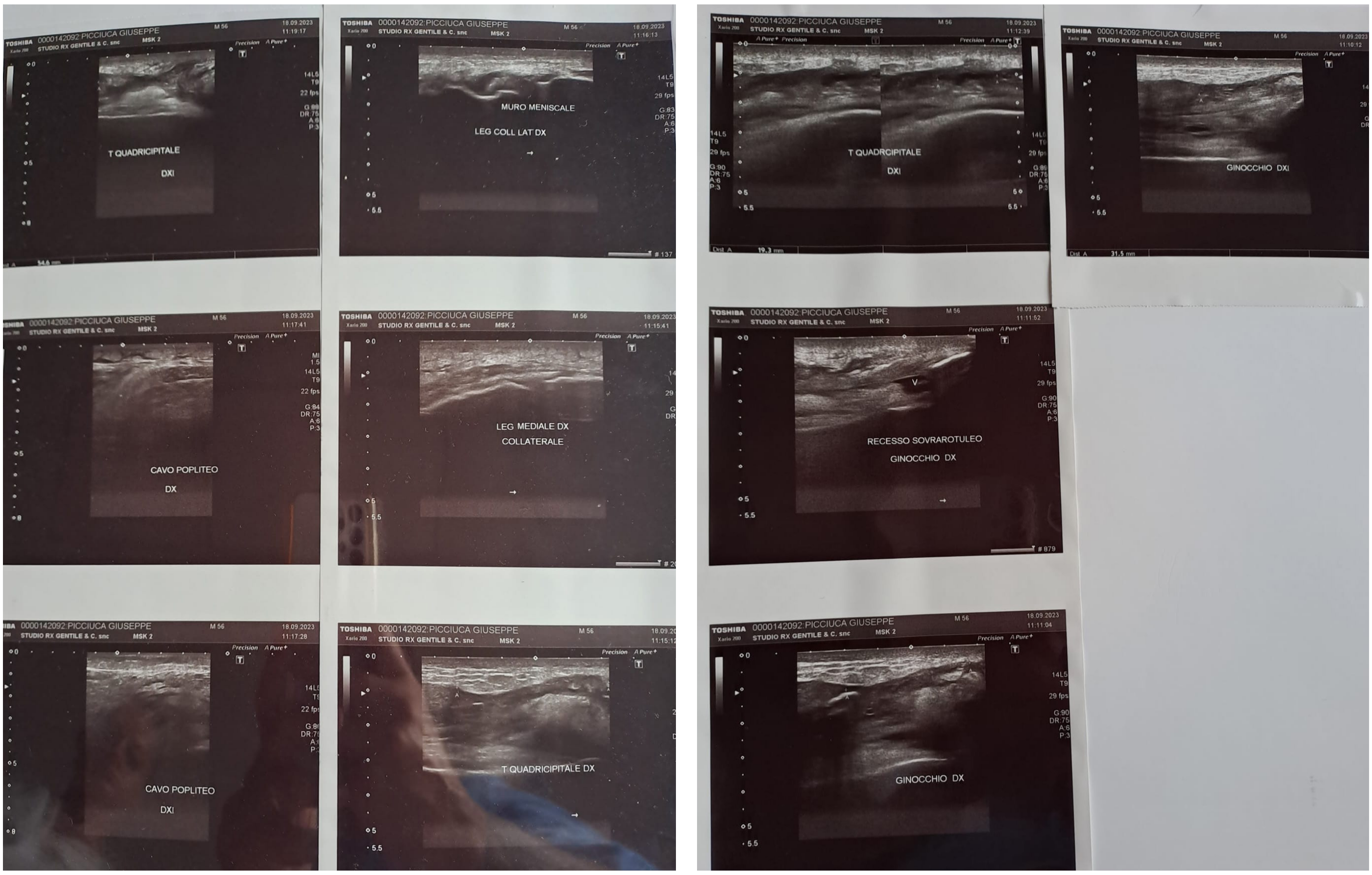

Figure 1-2: Patient A

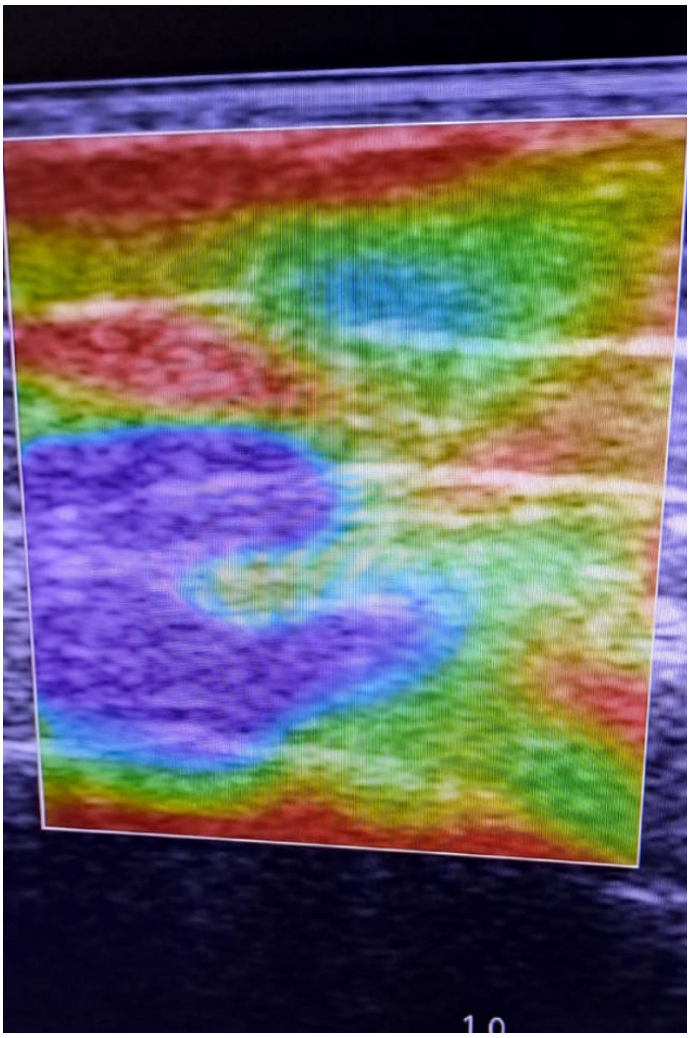

Figure 3: Patient B

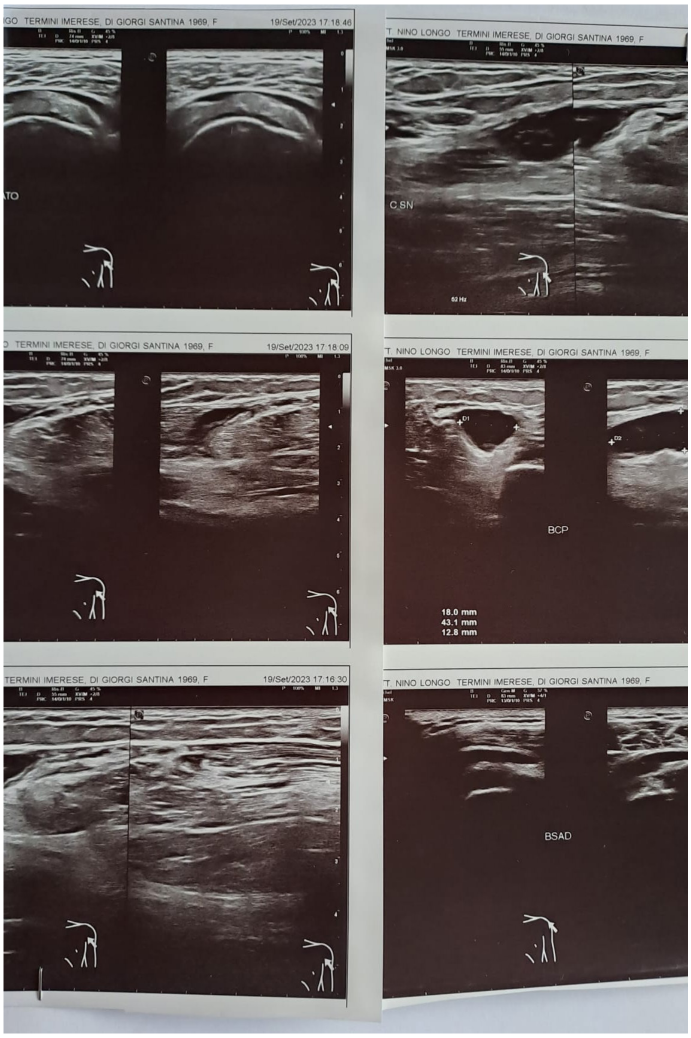

Figure 4: Patient C

Patient A

MUSCLE ULTRASOUND OF THE RIGHT KNEE
REPORT dated 09/18/2023:
Rupture of the quadriceps tendon at the muscle-tendon insertion with detachment of the tendon from the patella, extending for approximately 5.5; the muscle fibers of the proximal stump appear raised and bundled with evident diastates and liquid collection in the same site, as well as a further small amount of liquid in the synovial sheath, in the distal site.
The finding is compatible with an almost certainly total rupture (the patient has undergone a further MRI examination which does not describe the details of the lesion) and is worthy of orthopedic surgical consultation, even if in relation to the neurological pathology it is necessary to evaluate possible conservative treatment.

- Moderate effusion layer in the suprapatellar recess.
- The patellar tendon is normal.
- Collateral ligaments are regular.
- Protrusion and hyperechogenicity of the lateral meniscal wall compatible with meniscosis; minimal protrusion of the medial meniscal.
- Absence of Baker's cyst in the popliteal cavity.
- Finding compatible with gonarthrosis.

The patient reports that he was injured on 08/29/2023 following an accidental fall caused by weakness of the left lower limb following post-traumatic hemiparesis, the patient did an echo and MRI of his right knee.
Eol: the patient walks independently with the help of a crutch, moderately altered gait pattern (result of hemorrhagic stroke).
The clinostatism is noted: right knee normally extended, patellar rolling +-, active flexion 120°; active knee elevation possible starting from a sitting position; upon palpation, no areas of minus can be noticed in the suprapatellar area which may refer to interruption of the quadriceps tendon.

There is currently no surgical indication. It is prescribed: to insist on the rehabilitation protocol that's already been successful, paying particular attention to the control of the residual inflammatory process and the optimal recovery of ROM muscle tone.

Figure 5: Patient A treated with Cryosound

Patient B

MRI KNEE AND LEFT LEG
REPORT:
The MRI examination of the left knee, performed using sagittal T1W and STIR, axial DE and coronal STIR scan planes, highlighted:
MEDIA BEHAVIOUR
- in fibrocartilage meniscosis, a degenerative lesion of the posterior horn near the tibial attachment with medial displacement of the body; there is an area of minimal intraspongious edema in the corresponding underlying medial-posterior region of the tibial hemiplateau
- osteochondral alteration with perilesional intraspongious edema affecting the femoral condyle
- outcomes of traumatic capsulo-ligamentous involvement of the proximal third of the collateral ligament, which appears to be inserted
CENTRAL PIVOT
ACL and PCL inserted
minimal, hazy area of intraspongious edema corresponding to the intercondylar spines
SIDE COMPACT
-meniscal fibrocartilage meniscosis
- collateral ligament inserted
Discrete endoarticular effusion with fluid distension of the recess of the gastrocnemius-semimembranosus (cyst of the popliteal cavity with a maximum diameter of approximately 5.9 cm).
Enthesopathy of t. quadriceps. Signs of proximal patellar enthesitis.
Moderate edematous imbibition of the superficial prepatellar soft tissues. Minimal fluid unlamination of the deep infrapatellar bursa.

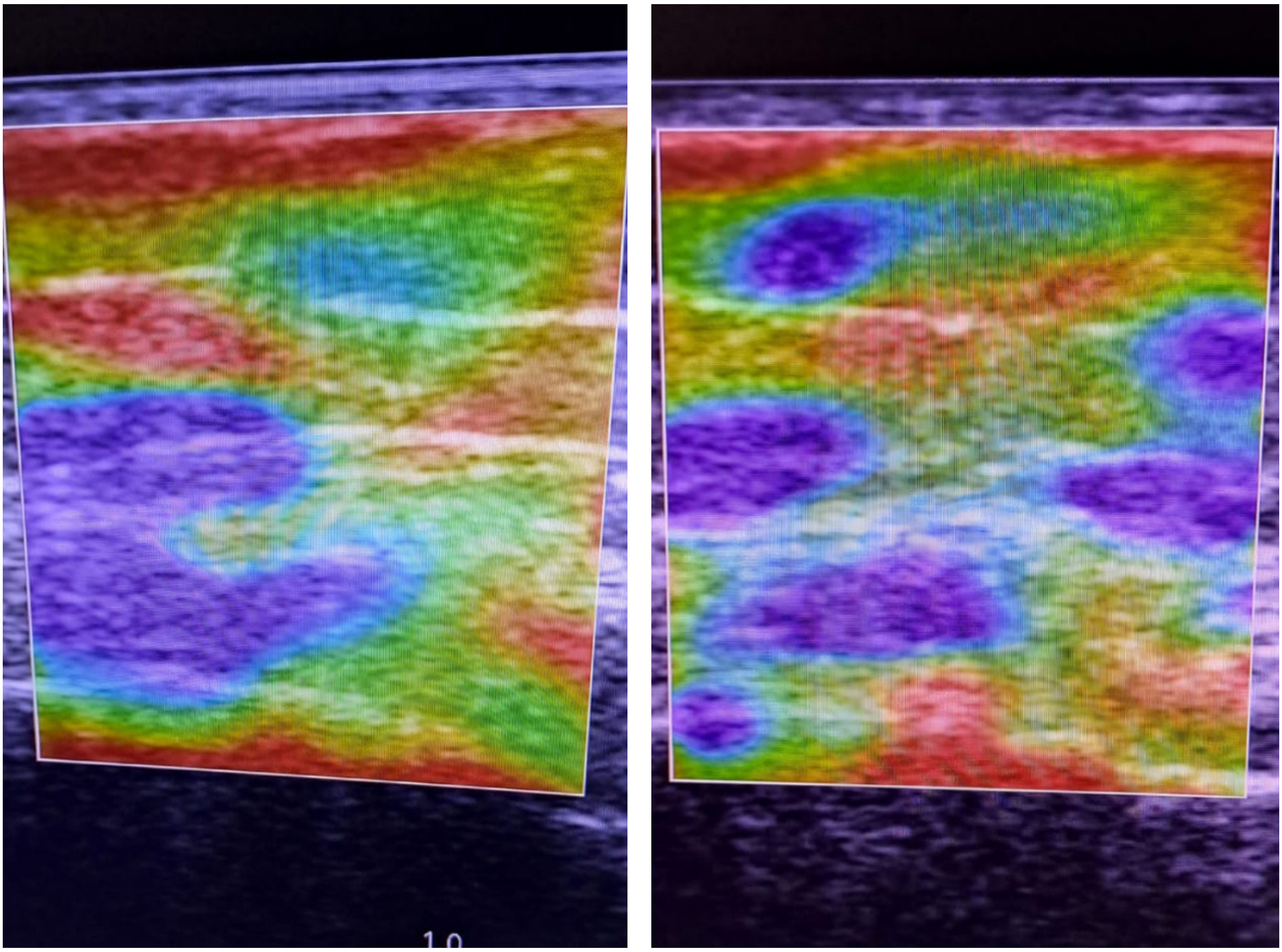

Figure 6: Patient B Elasto, pre and post therapy

Patient C

ULTRASOUND OF THE LEFT SHOULDER
REPORT
The ultrasound examination performed with a small parts linear transducer at high frequency on the left shoulder shows a subtotal rupture of the biceps brachii in correspondence with the proximal tendon with the presence, at the level of the rupture site, of a large area referable to a hematoma which presents a medial sac in which the fibers appear to be largely interrupted along their course, with the exception of a small number of survivors in the posterior area, from a subtotal rupture, and a lateral sac which is longitudinally for approximately 43 mm, with DT mx of approximately 18 mm and DAP of 12 mm, close to the muscle belly.
Marked increase in thickness with uneven hypoechogenicity of the capillary tendon biceps brachii with loss of the normal fibrillar pattern due to multiple tiny hypoechoic areas in which the tendon fibers appear rarefied, as if from intratissue ruptures.
Furthermore, a thin anechoic peritendinous layer of fluid type is appreciated.
Evident fluid distention of the subacromiodeltoid bursa.
Inhomogeneous hypoechogenicity of the suprapinosus tendon of tendinotic type.
The subscapularis tendon was never visible.

Conclusions

Patient A

At VAS 8 assessment; ROMp 40°; notable difficulty walking with flexum attitude and widespread edema of the lower limb.

While waiting for the surgical consultation, the objective of the treatment was to manage the increased tension of the flexors, of the edema and pain and improve the joint ROMp.
The treatment with Cryo Sound is carried out with a frequency of 1Mhz with a temperature of -2° and a dose of W/Cm2 of 1.80 (variable per session by monitoring the FEG).
Each session is combined with specific therapeutic exercise with the aim of limiting the increase in muscle tone of the flexors (consequent to the flexum attitude).
From the second session, a reduction in VAS of 6-7 and ROMp of 65° can be seen until reaching ROMp 85°, at the fourth session, with a notable reduction in VAS which goes up to 5.
The session is carried out using Cryo Sound in:

1. Static mode on the lesion and passive mobilization of the tibio tarsal to stimulate the lengthening of the posterior kinetic chain with relative and synergistic manual therapy;
2. In active mode with synergistic mobilization of the patella and flexion-extension of the knee;
3. Passive mode on the posterior compartment (patient prone-lateral decubitus).

Closed kinetic chain exercise with controlled ROM is included during each work session, to maintain the result achieved at a neurophysiological level, and counteract the excessive muscle tone of the flexors as a mechanism resulting from the injury.
While waiting for a new Echo, at the surgical consultation, the specialist doesn’t want to proceed with surgery, but he decided to continue with conservative treatment.

Patient B

Significant functional limitation with pain VAS 8, knee edema and ROMp 35°.
We proceed with treatment with Cryo Sound with a frequency of 1Mhz with an average temperature of 0° and a W/Cm2 dose of 2.00 in the posterior compartment and 1.50 in the suprapatellar compartment.
During manual work combined with instrumental technology, a joint pump was performed synergistically with passive patellar and joint mobilization techniques and stimulation of the correct recruitment of the quadriceps.
We start with the third session, post-treatment, horizontal exercise bike with wireless electrostimulation in synergy on the quadriceps for 15 minutes.
At the ultrasound check, after the sessions carried out, the cyst of the popliteal cavity reduced from 5.9 cm to 3 cm.
Furthermore, during the treatment the elastic tissue compartment (FEG) was monitored and changed after each session.
Pain reduction VAS 3-4, ROMp 90°. The specialist proceeds with a cycle of infiltrative therapy with hyaluronic acid.

Patient C

At evaluation patient with pain VAS 7-8 with major functional limitation in extension and edema.
Treatment carried out with a frequency of 1Mhz with a temperature from 2° to -2° with W/Cm2 of 1.50.
The treatment was carried out in static, passive dynamic and light resistance-resisted modes in extension across the entire biceps muscle.
Post-treatment, ETC is required to be performed on panels with the aid of Taping, in order to stimulate the muscular synergies of the upper limb between agonist and antagonist. Post-treatment VAS 4. Almost complete recovery of ROM.
Awaiting ultrasound evaluation.

Publication by C. LISI (AO Policlinico San Matteo), C. COSTANTINO (Orthopedic Clinic, University of Parma) and A. AMMENDOLIA (Orthopedic Clinic, University of Catanzaro "Magna Græcia", Italy).

Among instrumental therapies with physical treatment, therapy with ultrasound is one of the most frequently used. From a review of the literature, slight evidence emerges of their therapeutic efficacy in the treatment of tendinopathies compared to placebo; However, ultrasound therapy has maintained an important role in the treatment of inflammatory-degenerative tendon pathologies.
Cryoultrasound is an innovative device that bases its operation on the synergism of two therapeutic techniques such as cryotherapy and ultrasound therapy which, by interacting and strengthening each other, reduce the thermal effect to the advantage of the mechanical one and a significant reduction in temperature on the application site. This allows it to be used even in the acute phases of inflammatory tendon pathology with the aim of blocking the evolution of the process and ensuring a early functional recovery of the athlete.

Methods

In order to observe the clinical results obtainable with the application of this new therapeutic method, in 2004 a prospective longitudinal multicenter study was conducted on a total of 162 patients (average age 34.3 years), practicing sport at a competitive and amateur level , affected by tendinopathies or enthesopathies in the acute and/or subacute phase.
Patients recruited for the study met the following criteria:

- absence of metabolic pathologies, coagulopathies, arteriopathies, ulcers and/or skin wounds, phlebothrombosis, thrombophlebitis, tumors;
- absence of alteration of thermopain sensitivity;
- absence of intolerance to cold;
- inflammatory pathology that began less than 1 month ago;
- no associated physical therapy.

For the clinical evaluation of patients the following parameters were taken into consideration:

- ache;
- functional limitation.

All patients did an ultrasound examination before treatment and after the last therapeutic session. The patients followed the same protocol based on 10 applications on a daily basis (5 per week) lasting 20 minutes each, with a power of 2.2 W/cm2 and a temperature of –2° C. The evaluation of the results was obtained using a VAS scale for pain and a WOMAC card for joint function.

Results and discussion

The processing of the data made it possible to detect a clear improvement in subjective painful symptoms, in over 90% of cases, some of which already improved after the first five sessions. As regards functional recovery, the percentage of improvement was approximately over 80%.
A follow-up treatment was done 3 months after the end of the therapy, which highlighted the results obtained.

Conclusions

The continuation of the study, especially with the addition of control and comparison groups, will probably allow more significant results over time.
The results obtained so far and their maintenance certainly encourage the treatment of tendinopathies in athletes with Cryoultrasound.

Cryosound, pain at the right elbow, radiating to the entire forearm, exacerbated by wrist movement, gripping objects and with forearm muscle weakness

P.F., 35 years old, male. Construction company owner. For more than two weeks he has reported pain in the right elbow, radiating to the entire forearm, exacerbated by wrist movement, gripping objects and with muscle weakness in the forearm.

We used cryoultrasound (Catania, Italy) for 10 sessions (5 sessions per week, for 2 weeks) with an average temperature of 0°, a dose W/cm2 of 1.00, at a frequency of 3 MHz, for a duration of therapy of 8 minutes per session, as shown in Figure 1.
At the beginning of treatment, a limited joint excursion of 10° in right elbow flexion, a Visual Analogue Scale (VAS) of 6, a quickDASH=40.9/100, a hand grip test (HGS) of 36.4 kg, on the right and of 41.8 kg on the left. Furthermore, with a shear wave elastography (SWE) analysis for lateral epicondylitis the patient demonstrated an average of 3.10 m/s on the left and an average of 2.39 m/s on the right.

At the end of the treatment, the patient reported a full range of motion of the right elbow, a VAS of 1, a quickDASH=15.9/100, a hand grip test (HGS) of 40.9 kg on the right and 42.1 kg on the left. Finally, during the shear wave elastography (SWE) analysis, the patient demonstrated an average of 3.19 m/s on the left and an average of 2.99 m/s on the right.

Figure 1. Cryo-ultrasound therapy device

Giuliano Mari, physiotherapist at the Medben center in Rome, has chosen Medical Cold Therapy, once again, by purchasing the new Cryosound

"Ultrasound in physiotherapy is certainly not new as it has been used since the 1950s. The innovation of cryoultrasound is to combine the ultrasonic with a cold source which allows the effects of the ultrasound to be maximized.
Ultrasound therapy essentially produces 2 therapeutic effects:

- Thermal effects;
- Non-thermal effects.

Thermal effects consist in heating the target tissue of the ultrasound waves. The part of the tissue that heats up the most is certainly the skin, therefore, to produce a peak of heat, in depth, a cooling source was combined. The interaction between the two sources produces the heat peak.
Non-thermal effects can be divided into cavitational and non-cavitational effects. Cavitational effects consist of the formation of microscopic bubbles within the tissues. These bubbles will produce free radicals which will have an anti-inflammatory action.
Non-cavitational effects are the mechanical effects of ultrasound. Since the ultrasound wave has a wavelength comparable to the size of the cell, in the past it is said that ultrasound performed a real cellular massage."

This device is therefore particularly effective on:

- Tendonitis;
- Tendinopathies;
- Intratissue calcifications;
- Plantar fasciitis;
- Muscle injuries;
- Carpal tunnel.

Alessandro Pernice, physiotherapist and osteopath of Torino FC talks about his experience with the Cryosound + Thermal Shock device

“We use Cryosound in all phases of our players’ injuries, especially in the acute and sub-acute phases (such as muscle injuries and joint sprains), significantly accelerating recovery times. The possibility of modifying the work settings allows us to use it in chronic treatments such as tendinopathies, muscle injuries (using thermal shock), for scarring and for lymphatic drainage.

We find the option with arm for non-operator dependent therapy very useful in our organisation, it allows us to optimize working times with excellent results. When we have several players to work with at the same time, it is ideal for us to leave the 70 mm head on the desired area and set the treatment. The therapy is quick, lasts about 25 minutes and the immediate analgesic (and anti-edema) effect makes it very comfortable for our players.

Thanks to its size and the carrying bag supplied, we are able to use it on all the trips that our team faces and the therapies available with the Cryosound are of great help to all the medical staff.”

Torino FC and our Cryosound, club doctor Corrado Bertolo tells us how he uses the device to treat Granata players

For which pathologies and which anatomical areas do you use Cryosound on footballers?

The football environment implies that the most stressed joints are the knee and ankle, but we have also covered the shoulders and the trochanteric regions, especially in goalkeepers. About pathologies we work all tendinopathies and everything that concerns muscle injuries (therefore also the larger districts). The Cryosound has also been used in the outcomes of traumatic events such as shoulder dislocations, therefore in post-physiotherapy recovery, in dislocations clavicular acromion and in early post-surgery stage.

Which feedback do you get from players who have been treated with Cryo Sound?

Athletes immediately report a significant analgesic effect and, more in the long term, a significant facilitation in the execution of physiotherapy courses, therefore with a reduction in pain they have a faster recovery.

In which working phases do you use the Cryo Sound?

It covers all the work phases, which can be useful for an athlete available for small overloads, or on athletes that stopped playing due to injury, both in the early phase and more chronically, obviously changing all characteristics.

In which pathologies do you use thermal shock?

Thermal shock is slightly less useful in our field, but I would say that the pathologies where we have used Cryo Sound the most are muscle injuries and tendinopathies.

Dr. Antonio Ventrella, owner of the Fisiohome studio, talks about his experience with Cryosound

"For about six months we have included the Cryosound + Thermal Shock product from Medical Cold Therapy in our center. The device is proving to be an excellent tool for the treatment of various pathologies. Initially, we thought of using it only for the treatment of pathologies in the acute phase but its versatility amazed me, revealing itself as a tool to also be used on sub-acute and chronic patients.

Cryosound is a versatile and functional device: by promoting the reduction of edema and carrying out an analgesic action, it is suitable for all treatments of pathologies in the acute phase (for example, ankle and knee sprains) and post-operative treatment of all patients who had surgical operations (especially knee, shoulder and hip replacements) as well as the treatment, in general, of all muscular pathologies such as strains and elongations. Furthermore, the possibility of also using thermal shock makes it a truly complete device.

I would like to also add that the Medical Cold Therapy staff, at our request, gave us a specialist with whom we had a training Zoom in which we had the opportunity to discuss the most of the potential of the equipment.

In light of the excellent results obtained with its use, I highly recommend it to all my colleagues."

Dr. Leonardo Gini, owner of the Fisio LG studio in Livorno, talks about his experience with the Cryosound device

“Cryosound is an excellent machine, because in addition to the ultrasound treatment, it also allows us to use the action of cryotherapy at the same time. This is a fundamental aspect in the rehabilitation field, because it allows us to work immediately on problems and pathologies in the acute phase, we are able to work by drawing a reduced quantity of blood, a result that is not possible to obtain with other treatments such as Tecar therapy or Laser therapy. In our practice, the pathologies most treated with Cryosound are muscle trauma, such as the treatment of edema, injuries and contusions. Also recommended for arthritic processes, bursitis and all inflammatory processes, especially insertional and non-insertional tendinitis.

A special mention is the excellent effectiveness found especially on arthritic pathologies. Cryosound allows us to obtain both a strong drainage and an anti-inflammatory effect on the entire cartilaginous part. In just a few sessions we were able to reduce the patient’s pain, obviously without neglecting all the problems that an arthritic pathology can bring.

Another very effective field Cryosound can be used on is the first phase of a muscle tear, where we are able to both contain the blood flow and start draining the wound which will be obviously treated with laser therapy.

Furthermore, with the Cryosound we can also work on a thermal aspect, i.e. having thermal shocks going from colder temperatures to very hot temperatures with biological effects of considerable advantage for the rehabilitation activity, allowing a faster and more functional recovery.”

Francesco Massara, physiotherapist, decided to make use of Cryosound technology thanks to the advice of a colleague who already knew the results of ultrasound combined with cryogenic therapy

Doctor Massara, what pushed you to buy Cryosound?

I already had an ultrasound device and I know how effective they are, but my old device didn't have thermal shock. I treat many Padel players, where traumas due to the racket (elbow, shoulder, etc.) allow me to use the Cryosound immediately with incredible results: there is an immediate reduction in pain and thanks to the cold I am able to use higher powers in terms of watts with faster results.

Do you use it in manual mode or with the fixed arm?

I usually combine Cryosound therapy with kinesis if I treat a region such as the shoulder for example, but if I treat a limited area I use the fixed arm in pulsed mode with temperatures slightly above zero to avoid creating cold burns.

Do you use thermal shock?

Of course I use it! Going from cold to heat (or vice versa) is very effective as vascular gymnastics and is particularly suitable for post-muscle injury situations. Furthermore, I often use Cryotherapy without ultrasound in subjects where it is not possible to use this method or, for example, after a Tecar to close the treatment on an acute phase.
I must say, to my great surprise, I use this device as much as a Tecar, so I can only recommend it!


Temperatura
-4.0
Freq.
Durata Trattamento
02 : 39

MEDICAL COLD THERAPY

CRYO SOUND

DISTRIBUTOR

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