

Pulsed Nd:YAG laser and thermal exchange: a new therapeutic strategy in pain management. Experience on 100 patients.

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ABSTRACT

HIRO TT is a new thermal exchange therapeutic strategy which is based on thermal gradients originated by the association of Hilterapia® with a cooling system which lowers the temperature of the skin and the underlying tissues, called SmartCooler. The aim of this study was to evaluate the effect of HIRO TT treatment on pain and function in neuromuscular and osteoarticular pathologies. One hundred consecutive patients treated with HIRO TT strategy during routine practice in two centres were assessed in terms of VAS scale and functional changes before and after the treatment. On a selection of patients, ultrasound and MRI examinations were carried out before and after the treatment to assess any changes due to treatment. The more common diseases for which the patients have been treated were: trauma,

edema, contractures, tendinopathies, and arthritis/joint pathologies.

No side effects were reported. Significant improvements were obtained after the treatment in terms of VAS decrease, and functional recovery. After the treatment, most of the patients (81,25%) were completely pain free (VAS=0). Ultrasound evaluation demonstrated the effect of the treatment on contracture area relaxation, edema resolution and local microcirculation improvement. MRI showed a consistent improvement in edema and inflammation, regardless the anatomical location and the type of condition that was treated.

The thermal exchange treatment with the HIRO TT system demonstrated to be a safe and effective therapeutic strategy in the treatment of pain associated with several conditions affecting the musculoskeletal tissue.

INTRODUCTION

Musculoskeletal disorders are common conditions and represent a high cost for the public health system (1). These conditions are the most common cause of chronic severe pain and physical dysfunction, affecting hundreds of millions of people worldwide. Some of these conditions are associated with aging, such as knee osteoarthritis, others are typical of young and active population, for example muscle lesions due to sport activity, but all of them are associated with pain and functional impairment, ranging from discomfort to limitation of professional ability. In fact, chronic pain causes sleep interruption, fatigue, depression, activity limitations and participation restrictions (2). The neck and back are the most common areas of musculoskeletal disorders, followed by the upper limbs and lower limbs (3). The goals of musculoskeletal condition treatment are to modulate inflammation, relieve pain, improve functionality and, in general, to improve quality of life. Traditional therapeutic approaches in musculoskeletal pain management are based on nonsteroidal anti-inflammatory drugs, exercise, and physical therapy.

HIRO TT is a new thermal exchange therapeutic strategy which is based on the association of Hilterapia® and a cooling system which lowers the temperature of the skin and the underlying tissues, and it used in combination with stretching or functional exercise. Hilterapia® is based on a 1064nm pulsed Nd:YAG laser and has been reported to have anti-inflammatory, anti-edematous, and analgesic effects (4,5), along with proven clinical efficacy in pain management of a variety of neuromuscular and osteoarticular conditions, such as neck pain (6) low back pain (7,8), Achilles tendinopathies (9), subacromial impingement syndrome (10), myofascial pain (11), osteoarthritis (5,12), muscle lesion (13). The cooling system which lowers the temperature of the skin and the underlying tissues, called SmartCooler, is a Peltier-based technology and allows for a controlled decrease of tissue temperature,

ranging from 28°C to 18°C.

From the point of view of biological processes, the SmartCooler application allows a prompt skin temperature decrease, resulting in a cooling chain reaction involving the subcutaneous layer and, eventually, the deeper muscle layers. Early effects comprise modulation of the local microcirculation, muscle relaxation and reduction of the speed of pain conduction. The thermal gradients which are created by the alternated application of SmartCooler and laser determine a thermal exchange process among different tissue layers which enhances the microcirculation process and the lymphatic drainage, promotes repair processes, restores tissue homeostasis and prolongs the muscle relaxation action. In details, skin exposure to the SmartCooler stimulates the cold-sensitive thermoreceptors, which turns in local vasoconstriction and skin thermal isolation. As a consequence, arteriovenous anastomoses open allowing the blood to by-pass the capillary network and flow directly in the venules, resulting in a skin vasodilation associated with a marked, temporary temperature increase (Figure 1). This action on microcirculation is able to favour the drainage and improve edema resorption.

The combination of the SmartCooler action on subcutaneous axon endings and muscle spindles, which decreases nerve conduction velocity, along with Hilterapia® effect on fluid viscosity and tissue stiffness results in an analgesic and muscle relaxation effect.

Once the cooling effect reaches deeper layers, effects such as inflammation modulation and oxidative stress reduction are exerted. Moreover, the cooling effect allows for early interventions in acute cases, such as trauma or edema, by balancing the thermal component of Hilterapia®.

On arthritis and other joint conditions, the SmartCooler can boost Hilterapia® action by balancing the laser thermal component, allowing the treatment also in patients which are sensitive to heat. Additionally, Hilterapia® has a role in inflammation modulation and

the SmartCooler may counteract MMP action, in particular by inhibiting collagenase, thus protecting cartilage from degradation.

The HIRO TT strategy is based on the synergy of the combination of Hilterapia® and SmartCooler that results in an empowered analgesic and anti-inflammatory action. Association with stretching exercises is recommended, whenever possible, to improve functional recovery.

MATERIALS AND METHODS

One hundred consecutive patients from the routine practice of two clinical centers (Mediperson Centro Diagnostico Terapeutico-Pavia; Italy and Fisiolab-Vicenza; Italy) have been evaluated. Demographic details (i.e. sex, size, professional occupation) were collected. Diagnosis and instrumental evaluation (i.e. X-Ray, Ultrasounds, CT, MRI), when available, were recorded. Additionally, patients were evaluated by the specialist performing the treatment before

therapy start.

The HIRO TT protocol consisted in the SmartCooler application followed by, or together with, Hilterapia® treatment, according to the specific condition. Stretching exercises were further associated for the treatment of contractures and tendinopathies. Functional exercise was part of the protocol for joint pathologies. Hilterapia® parameters were chosen according to the patient characteristics, the condition and the condition phase (i.e. acute or chronic), dose ranged from 240 to 1780 mJ/cm², while total energy was comprised between 400 and 3501 Joule, according to patient, condition and condition phase. SmartCooler temperature setting varied from 18°C to 24°C, according to the condition to be treated.

HIRO TT system (ASA Srl, Arcugnano, Vicenza, Italy) was used. The laser works with pulsed emission (1064 nm), high peak powers (>3 kW), high levels of energy

Figure 1 - Microcirculation scheme: SmartCooler application stimulate a chain reaction which opens the arteriovenous anastomoses, allowing blood to bypass capillaries and flow directly from arterioles to venules.

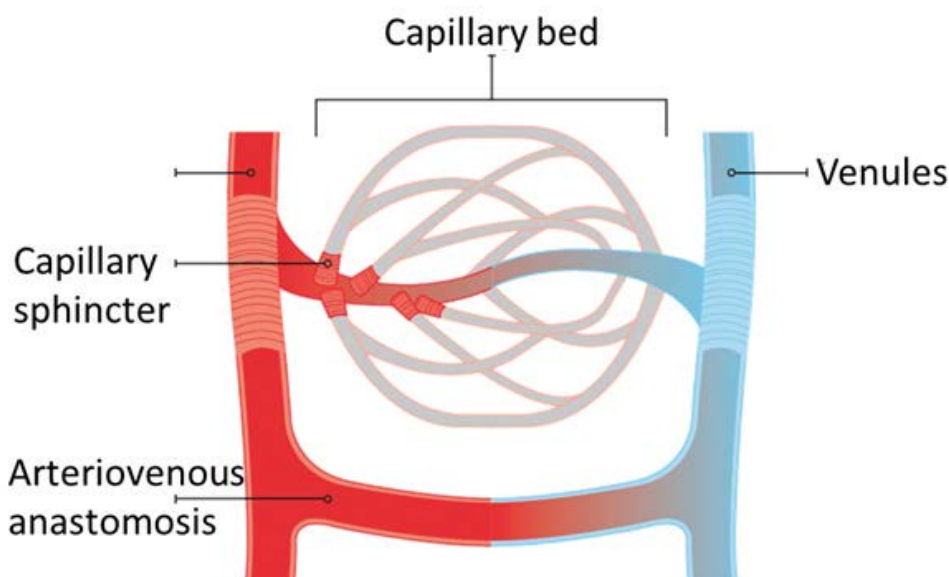


Table I - Patient characteristics.

Sex	31 Female 69 Males
Size (data available on 68 patients)	18% S 69% M 13% L
Available evaluation	25 Ultrasounds 15 RX 13 MRI
Professional occupation (data available on 58 patients)	Physically demanding 28% Non-physically demanding 72%

Table II - Diagnosis groups

Diagnosis group	Number of patients
Contractures	30
Tendinopathies	29
Traumas	11
Joint/arthritis conditions	14
Edema	5
Others	11
Total	100

density (fluency from 90–1.780 mJ/cm²), short pulse duration of (100 μs), a duty cycle between 0.1% and 0.3%, and frequency (10–30 Hz). The laser system has 3 different handpieces, which were used according to the condition to be treated: 1) DJD (degenerative joint disease), dedicated to therapies at the intra-articular windows of the joint, 2) 5 mm diameter handpiece, for pain therapy and trigger point treatment, 3) 10 mm diameter, that has a larger spot to spread the energy, specifically dedicated to the treatment of sensitive areas. For most of the patients, manual therapy

and home exercising were also associated to the HIRO TT treatment.

The total number of sessions was adjusted based on each patient response to the treatment and ranged from a single session, in a post-marathon muscle treatment in an athlete, to 10 sessions in chronic pain, i.e. pain associated to degenerative conditions such as knee arthritis.

Assessment of pain was performed using the VAS score before and after each treatment session, the evaluation of the pain reduction effect was done considering the first session before treatment value and the last session

after treatment value. The VAS is used frequently in clinical and research settings and it has been shown to be a reliable and valid measure of pain (14). Observations on changes in functionality, in edema (if present) and overall evaluations after the treatment were collected. Safety information were collected for all the patients.

Using an Esaote MyLab Six (Esaote Spa, Genova, Italy), ultrasound evaluations were performed on 7 cases, representing the following selected conditions: tendinopathies, muscle contracture, edema. Using an Esaote O-scan (Esaote Spa, Genova, Italy), MRI evaluations were performed on four patients representing the following selected conditions: arthritis, tendinopathies, acute trauma. The evaluation was performed using XBONE T2 sequences, acquire on sagittal, coronal and axial planes. Images were analysed using the OsiriX MD software, which is validated for clinical use in medicine (FDA, CE, ANVISA).

RESULTS

The demographic characteristics of the 100 patients involved are summarized in Table 1. On a diagnostic basis, the patients were divided into 5 groups. The number of patients for each group is reported in Table 2. VAS assessment was carried out on the overall patient population and separately on specific diagnosis groups and reported in Table 3. Results were analysed considering on the comprehensive population of treated patients and subanalysis was performed on patients that were more representative of the clinical practice. This means that a specific analysis was done on patients with VAS values >5 and that attended at least 4 treatment sessions.

Tendinopathies: twenty-nine patients presented tendon problems, 59% affecting the upper limb tendons, 38% affecting the lower limb tendons and 3% affecting paravertebral tendons. VAS values are reported on table 3. Remarkably, all the patients in the group with higher VAS and that attended >4 treatment sessions were

Table III - Results

	VAS baseline (all)	VAS end (all)	VAS baseline (selection)	VAS baseline (selection)
Tendinopathies	7	0.1	7.7	0.4
Edema	NA	NA	NA	NA
Muscle contractures	6.5	0.1	7.4	0.1
Joint/arthritic conditions	7.8	0.5	8.4	0.5
Traumas	4.9	0.6	7.3	0
Others	7.2	0.4	8.1	0.5
Total	6.7	0.5	7.8	0.3

Figure 2a and 2b - DeQuervain syndrome - MRI pre and post treatment to venules.

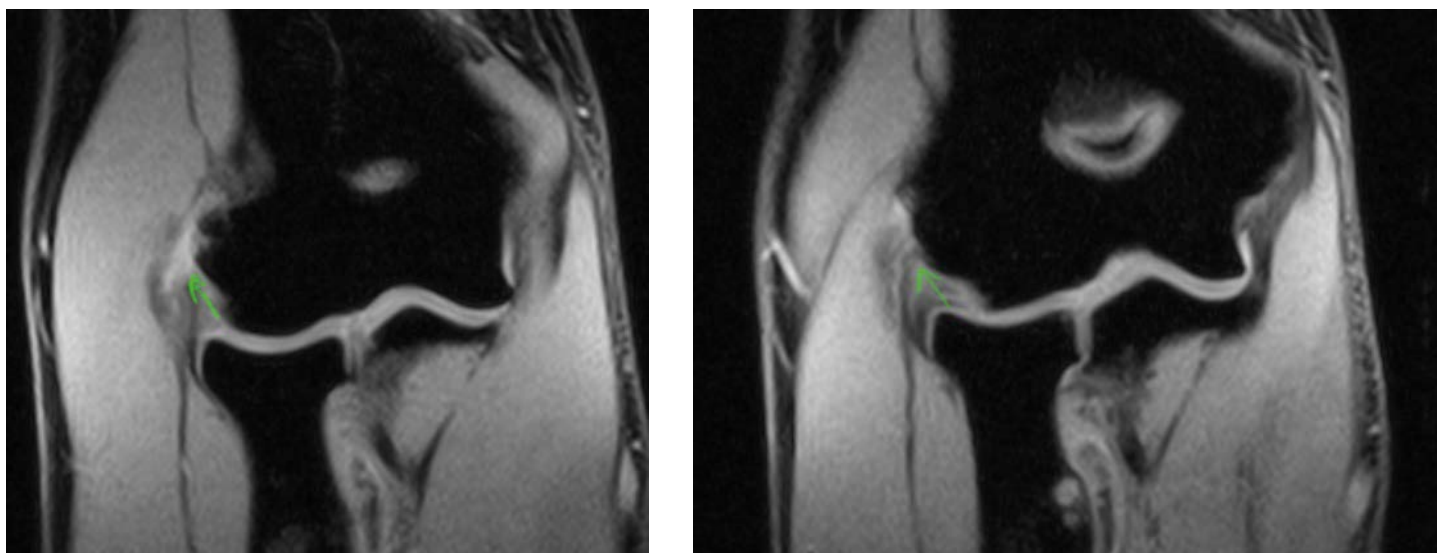
pain free at the end of the treatment. MRI was used to assess two patients presenting tendinopathies: one was affected by De Quervain syndrome and the other by tennis elbow. MRI scans were done immediately before and immediately after the first treatment session with HIRO TT.

Before treatment, the patient with De Quervain syndrome presented tendon sheath with an important inflammation. Articular inflammation was also present, without bone lesions, suggesting an over-use or post-traumatic condition, consistent with local edema and subchondral edema signs. Fibrocartilaginous tissue of the ulnar styloid process appeared degenerated. After the treatment with HIRO TT, collateral ligament edema was reduced, as well as the subchondral edema (Figure 2a and 2b).

The patient affected by tennis elbow presented evident edema and inflammation, demonstrated also by increased tendon thickness. After the treatment with HIRO TT, inflammation decreased and tendon thickness was reduced corresponding to an edema reduction of about 10%. (Figure 3a and 3b).

In conclusion, in the treatment of tendinopathies, best results were obtained in active patients in acute phase. Compliance with functional rest and/or functional exercise, according to prescription, is associated to earlier results. Additionally, range of motion improved after the treatment.

Edema: despite pain was not the primary reason for seeking the treatment, significantly, all the patients were pain free (VAS=0) after the treatment, regardless to the baseline VAS value, which ranged from mild to severe (VAS from 3 to 8). In most of the cases, knee intra-articular swelling was treated, which was often associated with high level of inflammation. In all cases, the results on edema reduction were rated as optimal by the evaluators. Ultrasound scan was used to assess the effect on edema area after the first treatment session, for example, a 20% reduction of the popliteus

Figure 3a and 3b - Epicondylitis - MRI pre and post treatment.

sheath diameter is shown in Figure 4a and 4b, demonstrating the biological effect of HIRO TT treatment on this condition. To treat edema patients, SmartCooler was set on 18°C-20°C and its application was able to improve the drainage of the fluids.

Muscle contracture: This group included cases of muscle contracture and strain, together with back pain patients with pain located at cervical or low back areas, in most of the cases due to postural causes. A total of thirty-one patients have been treated, corresponding VAS value are reported in Table 3. Among this patient population, the best results were obtained in active patients in the acute phase of the condition or in exacerbation of chronic conditions. It was overall noticed that the treatment of the contracted areas, not only was able to act on pain, but provided an improvement in the range of motion and, in general, in patient wellness conditions. For patients that had physically demanding jobs, working ability was also improved, contributing to the general quality of life of subjects. Three patients with contracture diagnosis were assessed by ultrasound scan immediately before and after the first

treatment session with HIRO TT. Figure 5a and 5b report the reduction in diameter of the contracted fascia (from 7 mm to 5.9 mm) in a patient treated on a trigger point. After the treatment, the trigger point zone echogenicity appeared normalised. For two patients, ultrasound scans were performed 3, 5 and 7 minutes after the HIRO TT treatment, demonstrating continuing improvement of the hypoechoic areas and myofibril structures, due to the thermal exchange processes induced by the thermal gradient creation.

Joint/arthritis conditions: fourteen patients were treated. Most of them (64%) were affected at the knee joint, other affected joints were cervical spine, finger and shoulder. Treatment of these patients involved the treatment of the muscle component and the articular windows. Important results were seen on edema, whenever present. Corresponding VAS values are reported in Table 3. To understand potential changes at the tissue level, one patient was assessed by MRI immediately before and immediately after a session with HIRO TT. At baseline, the patient presented a large effusion in the intra-articular synovial space, associated to an

important synovial cyst. A medial meniscal lesion and ligament associated edema were also observed. After the treatment with HIRO TT, edema was reduced in thickness and inflammation appeared improved. Figure 6a and 6b report on this patient knee MRI before and after HIRO TT treatment. In general, along with the progressive improvement in pain, function recovery was also observed that was potentially related to return to work, especially for patients with physically demanding occupation. In this group of patients, it was also observed that subjects who were more compliant in terms of attended sessions and adherence to therapist recommendations obtained the most satisfying results.

Trauma: This group included patients with sub-acute to medium recent traumas, involving both muscle and tendon structures. The use of the SmartCooler allowed for an earlier intervention. In most of the cases, the laser treatment was performed using the 10mm handpiece, therefore spreading the laser energy on a larger area for a more delicate approach. Swelling of tissues was often associated to the lesion area. For this group of patients, diagnosis was made

Figure 4a - Edema: Ultrasound image before treatment with HIRO TT.



Figure 4b - Ultrasound image after treatment with HIRO TT: edema reduction.

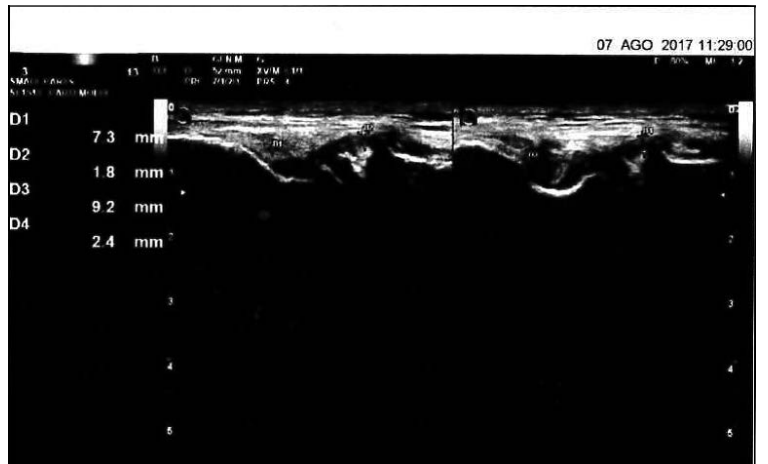


Figure 5a - Contracture: ultrasound before HIRO TT treatment.



Figure 5b - Contracture: ultrasound after HIRO TT treatment showing a reduction of the contracted fascia.

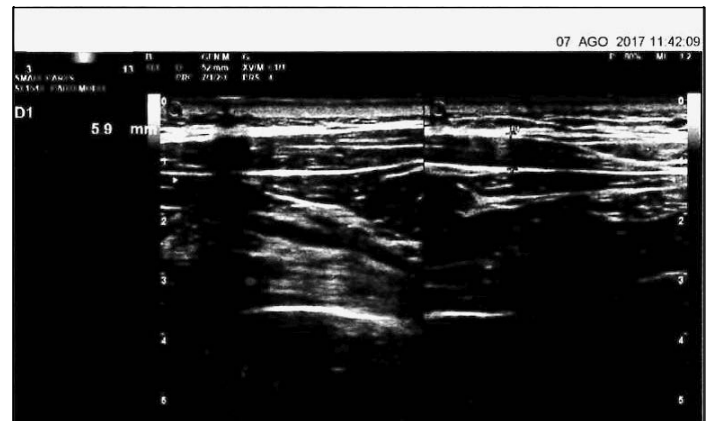


Figure 6a and 6b - Knee MRI before and after HIRO TT treatment.

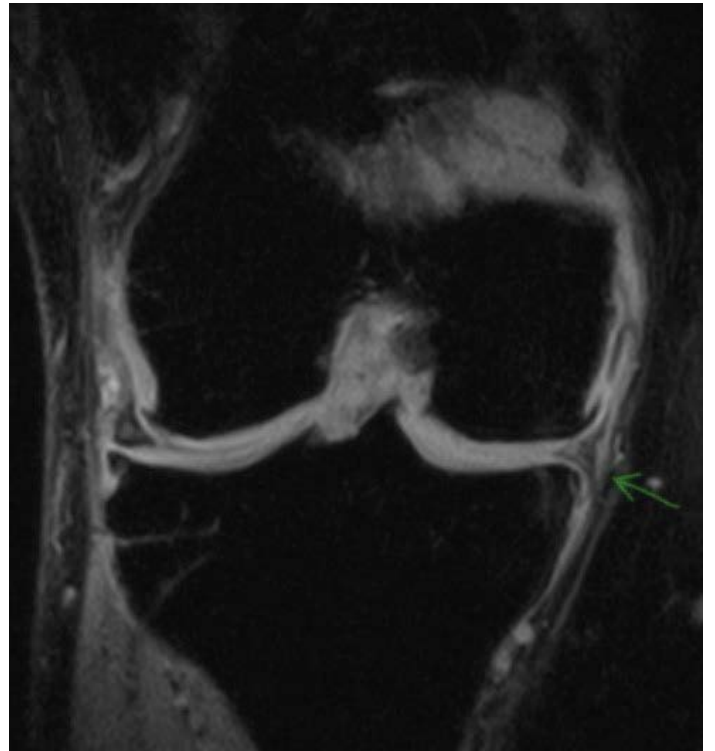
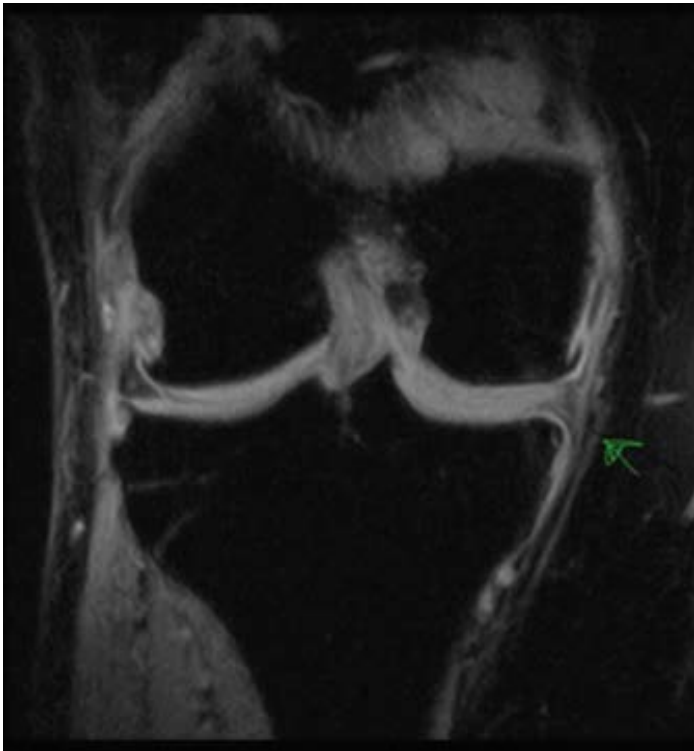
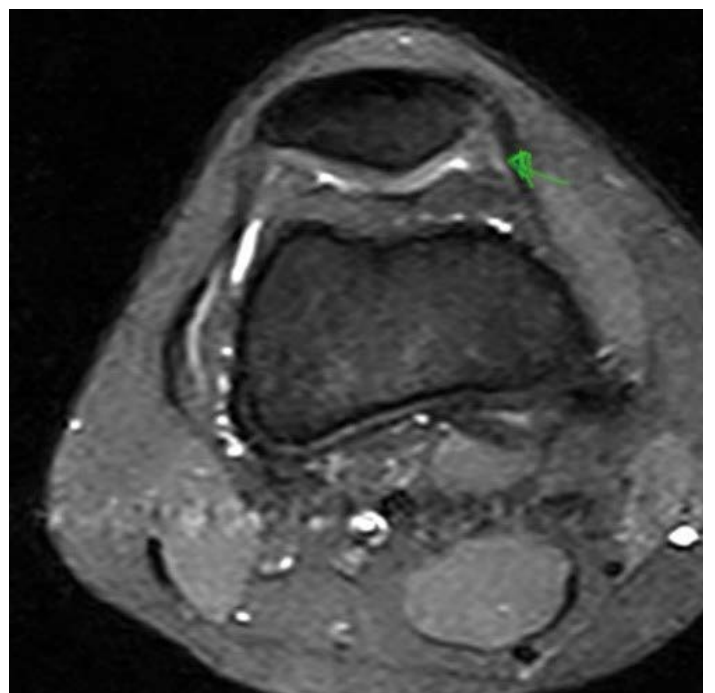
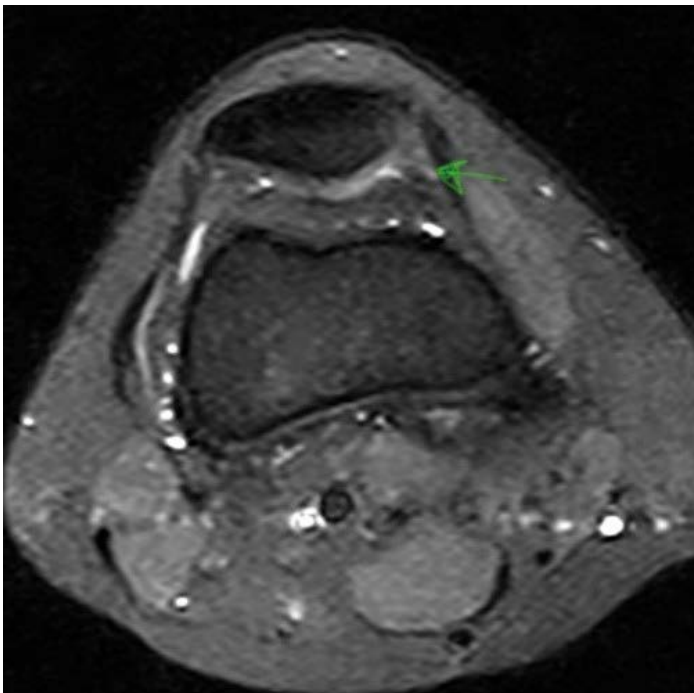


Figure 7a and 7b - Trauma - MRI pre and post treatment.



with the help of instrumental procedures. Corresponding VAS values are reported in Table 3. It was observed that in the group with higher baseline VAS (>5) and attending at least 4 treatment sessions, all the patients were pain-free after the last session. Remarkably, one patient with a lesion of the medial collateral ligament started the treatment with the highest possible pain score (VAS=10), which progressively decreased with HIRO TT treatment. After 9 sessions the patient reported to be pain free (VAS=0). In general, muscle lesion cases reported reduction in VAS score which was more evident after the third session, namely after 4-5 days from the treatment start. To understand potential changes at the tissue level, one patient was assessed by MRI before and immediately after a session with HIRO TT. At baseline, MRI showed an intra-articular swelling and over-use signs at the anterior cruciate ligament level (see Figure 7a and 7b). Edema was also reported in many areas, such as the collateral ligament, the cartilage layer and medial meniscal parts. After the treatment, edema was reduced in several points, corresponding to an anti-inflammatory action on the locally treated areas.

Others: this category includes different diagnosis not fitting in the main condition groups, such as metatarsalgia, bursitis, carpal tunnel syndrome, muscle fatigue after intense sport activity (marathon), hallux rigidus post-surgical recovery, thoracic outlet syndrome. Correspondent VAS values are reported in Table 3.

DISCUSSION

This collection of cases was conducted to investigate the effect of HIRO TT, combining pulsed Nd:YAG laser and the SmartCooler system and associating exercise, in 100 patients presenting different neuromuscular and osteoarticular pathologies by detecting changes in pain scale (VAS). Only patients that were treated with HIRO TT and functional

exercise were included. Some patients receiving kinesiotaping were allowed to be considered for the study, but other physical treatments, such as shock waves or capacitive and resistive electric transfer therapy, for example, were considered criteria for exclusion. Before receiving the treatment, patients were assessed for pain, active and passive ROM and strength. Overall, HIRO TT provided effective pain relief in the treated population. In details, optimal results were obtained for pain reduction, edema resorption and functional recovery. It can be observed that best results are obtained in young patients, in patients compliant to the treatment and with a good general health status. Nevertheless, the most important variable seems related to the quality of the tissue being treated. Ischemic areas, poor skin conditions, fibrotic connective tissue, muscle scar from previous lesions, or highly inflamed tendon sheath represent conditions that can impair final clinical results.

Considering all the VAS value collected, only 1 case presented a higher value of VAS after the treatment (VAS=2) respect to baseline (VAS=1), nevertheless this patient represented a particular case due to a very relevant emotional component and anxiety which has likely impacted on the treatment outcome in terms of perceived pain. Pooling together all the patients, the mean baseline VAS score was 6.7 and reached the score of 0.5 after the treatment. However, it is important to note that some of the patients were referred to treatment for reasons which are not related to the pain level itself (i.e. edema, functional limitations, etc). Whereas other patients had just attended a limited number of sessions (i.e. 1-3), which are not reflecting the real clinical routine. To reflect the most common situations that can be representative of the routine clinical practice, we have specifically focused the analyses on the patients which arrived at the first treatment with VAS (>5) and that

attended at least 4 treatment sessions. This number of sessions was chosen as in the authors' experience the most relevant changes in terms of pain happen after 4/5 treatment sessions. The outcome was an initial VAS of 7.8 and a final VAS of 0.3, underlining clearly the impact of the treatment in relation to the most painful conditions.

Single pathology categories have been assessed using this approach, confirming that the best results were obtained in the patients presenting the most painful baseline conditions.

Additionally, satisfying results were obtained in chronic patients as most of them was able to interrupt periodic infiltration therapy thanks to the possibility of managing pain and improving articular motion with a limited number of effective HIRO TT treatment sessions. This is the first report on clinical experience with HIRO TT and the result of this study are consistent with Hilterapia® safety and clinical outcome in pain treatment related to neuromuscular and osteoarticular conditions (6-13).

In summary, the thermal gradients, created amongst tissues at different depths after the alternating application of SmartCooler and Hilterapia®, generate a thermal exchange that: emphasises stimulation of the microcirculation function and lymphatic drainage, resulting in edema resorption, enhances reactivation of the biological repair processes, restores tissue homeostasis, prolongs muscle relaxation effect, speeds up functional recovery.

CONCLUSIONS

HIRO TT therapeutic strategy is a safe and effective treatment that combines Hilterapia® with a SmartCooler sometimes interspersed with physical exercises.

Clinical evidences show that the application of HIRO TT in physiotherapy and pain management gives significant results in terms of pain reduction in relation to a variety of conditions, such

as tendinopathies, muscle contractures, traumas, edema, articular/joint conditions and others. Promising preliminary results were also observed in terms of edema and inflammation reduction.

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