

# Report on the use of HIRO TT: validation of practice experience

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## ABSTRACT

This paper describes the clinical application of condition-specific practices using HIRO TT, a therapeutic strategy based on the combination of a pulsed Nd:YAG laser, a tissue cooling system and physical exercise. Data derived from 95 treatments carried out in two independent Italian physiotherapy centres. The conditions included in this analysis are: contracture (and trigger points), edema, tendinopathies, trauma and arthrosis. Overall, among the 5 analyzed conditions, the average decrease in reported pain was 90% after treatment completion.

## INTRODUCTION

HIRO TT is a new therapeutic strategy for treating painful conditions of the musculoskeletal system, based on the principle of thermal exchange. This therapeutic strategy is based on thermal gradients originated by the association of Hilterapia® (Nd:YAG pulsed laser source, a quite recent solution in the field of physical therapy) with a dedicated cooling system which lowers the temperature of the skin and the underlying tissues, called SmartCooler. Hilterapia® is a form of non-invasive laser therapy that demonstrated to be a valuable tool in the treatment of musculoskeletal disorders [1-4]. *In vitro* studies proved that Hilterapia® is able to induce photothermal

and photomechanical effects at cell and extracellular matrix level [5].

The application of the SmartCooler allows a measured decrease of tissue temperature (in the range 28°C-18°C) in the treated area. This triggers a unidirectional cooling chain which first involves subcutaneous layers and then the deep muscle layers.

Tissue cooling is a therapeutic strategy described in the literature for the management of acute and chronic conditions of various type [7-9]. Cooling causes vasoconstriction, reducing blood flow to compromised muscle fibres, decreasing the potential for swelling and producing less catabolic substances [8]. Intramuscular temperature remains below baseline for hours following cooling [10]. Tissue temperature has also an effect on neuromuscular function, as neuroconduction velocity has a direct linear correlation with temperature. Specifically, cooling is related to a reduction of pain sensation and of reflexive spasm thanks to the action on peripheral nerve structure [11].

Overall, the concept of HIRO TT is based on the synergy of the combination of Hilterapia® and SmartCooler. The thermal gradients which are created by the alternated application of SmartCooler and laser determine a thermal exchange process among different tissue layers. Early effects comprise modulation of the local

microcirculation, muscle relaxation and reduction of the speed of pain conduction [6].

Additionally, association with stretching exercises is recommended, whenever possible, with the aim to improve functional recovery. Nevertheless, exercises may not be used in patients presenting acute lesion of muscle and tendons or in the first therapeutic sessions of patients reporting very severe pain.

Since its introduction in 2017, HIRO TT is being used by physiotherapy specialists to treat pain due to several causes in a variety of patients. The first experience reported by early users was related to the efficacy of the treatment on 100 consecutive patients treated during routine practice [6]. In that large case series, no side effects were reported and significant improvements were obtained after the treatment in terms of pain decrease, evaluated with VAS scale, and functional recovery. During the collection of that clinical experience, given the fact that those centres were the very first to use the devices, the therapists spontaneously treated patients with highly personalised treatment modalities.

Beside the technical characteristics of the used device, the treatment modality represents a key point to be considered as it can contribute to the final clinical results. Therefore, practice suggestions on how to combine the different therapy elements (namely laser, cooling system and physical exercise) for optimal treatment have been developed and this report collects the clinical experience of two centers which have used HIRO TT on 95 treatments according to these practices with the goal of validating them.

Specific suggestions on treatment modality have been developed for the application on the most common conditions that are treated in physiotherapy centers. HIRO TT users confirmed that they have treated patients presenting a wide range of conditions, some of the most common problems are: cervical and back pain, rotator cuff tendinopathy, muscle strain, tendon

and ligament lesions, hematoma, joint acute and chronic problems. A distinctive feature of HIRO TT involves the possibility, thanks to the effect of the thermal exchange, to apply the therapy immediately in acute conditions, such as trauma, muscle lesions and contusions.

Based on those pieces of information coming from the field, the most common conditions have been grouped in classes and practice suggestions have been developed corresponding to the following categories:

- Contracture
- Edema
- Tendinopathies
- Trauma
- Arthrosis
- Trigger points

Virtually, any physiotherapy center could benefit from the inclusion of HIRO TT in its routine practice, but it is reasonable to think that different therapists may have different levels of experience with physical therapies and, specifically, with laser therapy and a variable confidence in the application of new therapeutic strategies. Therefore, the possibility of using validated treatment modalities which have demonstrated to lead to safe and successful results is an important support to allow early users to implement HIRO TT strategy at its best and reach the highest level of patient satisfaction.

Thus, the aim of this paper is to evaluate the clinical effect of practice protocols for the above clinical conditions. In any case, it is important to note that these practices are not intended to be a substitute for professional medical advice, diagnosis, or treatment.

## METHODS

The collected data are coming from the routine practice of two Italian physiotherapy centers: Fisiolab, based in Rosà (Vicenza – Italy) and Mediperson, based in San Martino Siccomario (Pavia – Italy). Ninety-five patients with different conditions

have been treated and assessed. Patients were considered in this report if they have received HIRO TT treatment following the practical steps and tips described above, while patients were not considered if they have received HIRO TT treatments which needed a high level of personalization due to the specific patient conditions or if they presented disorders that could not be included in the categories under the scope of this evaluation.

Patients were assessed for pain intensity using the VAS scale. VAS is a self-reported ordinal scale that provides reliable and consistent clinical measure of pain intensity. The VAS scale uses 11 points (0-10), where 0 represents “no pain” and 10 represents “the worst possible pain”. Each patient was asked to indicate the number on the scale that best represents the intensity of pain at baseline and after completing the treatment program.

Change in VAS from baseline to end of treatment cycle was assessed. At the conclusion of the treatment program, therapist's comments on general improvement features were recorded (i.e. functionality, range of motion, quality of life, etc.).

The average percent decrease in pain was calculated by:

$$\frac{(\text{pre-treatment VAS} - \text{post treatment VAS})}{(\text{pre-treatment VAS})} * 100.$$

Patients were treated with HIRO TT (ASA Srl, Arcugnano). The device gives pulsed emission ( $\lambda = 1064 \text{ nm}$ ), high peak power ( $>3000 \text{ W}$ ), high levels of energy density (fluency from  $90\text{--}1.780 \text{ mJ/cm}^2$ ), short pulse duration ( $100 \mu\text{s}$ ), a duty cycle between 0.1% and 0.3%, and frequency in the range  $10\text{--}30 \text{ Hz}$ , maximum energy per pulse ( $350 \text{ mJ}$ ), mean power ( $10.5 \text{ W}$ ), and power cycle of  $\sim 0.1\%$ . HIRO TT enables to connect the three handpieces ( $\varnothing 5 \text{ mm}$ ,  $\varnothing 10 \text{ mm}$ , DJD) with a single optic fibre and to combine them with the SmartCooler. The SmartCooler system consists in a Peltier plate for skin cooling, that can be regulated in the range  $18^\circ\text{C}\text{--}28^\circ\text{C}$ . The SmartCooler system

can be combined with the handpieces in a single applicator. Protective eye goggles were worn by the patient and the therapist. According to the diagnosed disorder, patients have received the treatments based on pre-set protocols and the practical steps that are reported below:

- Contracture

SmartCooler: the system was set to the temperature of  $+18/+20^\circ\text{C}$  and the cooled plate was applied to the contracted area. Intermittent applications of 5 seconds each x 3 on each treatment point were performed. Hilterapia® & Stretching: after applying the SmartCooler, laser treatment was carried out by scanning the contracted area using the appropriate handpiece ( $\varnothing 5 \text{ mm}$  or  $10 \text{ mm}$ ) and the pre-set treatment parameters in the “Muscular Contracture” program.

When possible, stretching exercises (muscle stretching) involving the contracted muscle were done simultaneously with the laser treatment.

- Edema

SmartCooler: the system was set to the minimum temperature of  $+18^\circ\text{C}$  and applied by scanning in the affected edematous area. Hilterapia®: after applying the SmartCooler, the laser treatment was carried out by scanning the area using the  $\varnothing 5 \text{ mm}$  handpiece and the pre-set treatment parameters in the “Edema” program.

The above procedure was repeated alternating the SmartCooler system and the laser handpiece for two or three cycles.

- Tendinopathies

SmartCooler: the system was applied point by point in the peri-tendinous and possible inflamed areas. Intermittent applications of 5 seconds each x 3 on each treatment point were performed.

Stretching: after applying the SmartCooler, when possible, stretching exercises (muscle

stretching) involving the muscles connected to the tendon were carried out.

Hilterapia®: after applying the SmartCooler, the laser treatment was applied by scanning the area using the Ø5 mm handpiece and the pre-set treatment parameters in the appropriate program for the tendinopathy to be treated.

- Trauma

SmartCooler: the system was set to the minimum temperature of +18°C and applied by continuously scanning the affected area for an adequate period of time in order to convey the temperature drop in a uniform and deeper manner to the affected area.

Hilterapia®: after applying the SmartCooler, the laser treatment was carried out by scanning the area using the Ø10 mm handpiece and the pre-set treatment parameters in the "Trauma/Contusion" or "Muscle Lesion – Acute Stage" program.

- Arthrosis

SmartCooler: the system was set to the minimum temperature of +18/+20°C and applied by scanning the intra-articular windows. Functional exercises: when the patient's conditions allowed this, after applying the SmartCooler the patient was encouraged to carry out small joint mobility exercises.

SmartCooler & Hilterapia®: the laser treatment was performed using the DJD handpiece and the "Arthrosis" protocol appropriate for the concerned area. Simultaneously apply the SmartCooler system & the laser handpiece by continuously scanning tissues through the intra-articular windows.

- Trigger points

SmartCooler: the system was set to the temperature of +18/+20°C and the cooled plate was applied to the trigger point. Intermittent applications of 5 seconds each x 3 on each trigger point were performed.

Hilterapia®: after applying the SmartCooler, laser treatment was carried out on the trigger

point, using the Ø5 mm handpiece and the pre-set treatment parameters in the "Trigger Point" program.

The aim is to reduce the initial pain by approximately 50-70%. For this purpose, the same step can be carried out one or more times, re-evaluating each time the pain of the treated trigger point through palpation.

Trigger point treatment is not a procedure *per se*, but it is carried out within the treatment of the specific conditions. The protocol suggested is taken by the suggestions for "Contracture" treatment, due to the fact that physiologically, the trigger point is a point of muscle hyper irritation and pain.

### RESULTS

Total treatments that had followed the practices are 95.

Results in terms of VAS changes for the pre- to post-treatment were reported in Table I, along with final therapist's comments.

All the protocols related to the practices

guarantee an average decrease in pain >85%.

Overall, among the 5 analyzed conditions, the average decrease in reported pain was 90% after treatment completion. Trigger point treatment is always part of another treatment session, therefore there is no specific VAS evaluation dedicated to TP and therefore it is not included in the calculation. Nevertheless, trigger point treatment is following the same concept of contracture treatment and can be considered validated by contracture protocol experience.

### DISCUSSION

HIRO TT is a new therapeutic strategy based on an integrated approach involving laser therapy, a skin cooling system and the execution of appropriate exercises. The effectiveness of this innovative approach has been described in a previous paper [6], where early users have described

Protocol Applied	Number of patients	Average VAS pre	Average VAS post	Average % decrease in pain	Therapist's Comments
Contracture	16	6.8	0.2	91.2%	Optimal results on all kind of patients, from obese sedentary to very active.
Edema	20	6.9	0.6	91.3%	Excellent results in edema reduction, which is the main treatment goal, along with pain decrease and improvement in functionality.
Tendinopathies	22	6.5	1.1	85.1%	Patient physical condition and pathology phase (acute or chronic) may have an impact on treatment results. Best results are associated to active patients and acute phase.
Trauma	13	7.5	0.5	93.3%	Optimal results. In particular, the treatment is useful as first line treatment to manage acute pain and therefore allow the patient to carry out recovery exercise.
Arthrosis	18	6.4	0.4	93.8%	Good results even in patients used to Hyaluronic Acid injections. In some patients, rebound effect was possible after first treatments, but it was anyway solved with treatment progress.
Trigger points	6	NA	NA	NA	Trigger point treatment is always part of another treatment session, therefore there is no specific VAS evaluation dedicated to TP.

**Table I** - Summary of the VAS changes in the treated patients.

the results of their routine practice using HIRO TT approach. Nevertheless, that patient series was treated with a highly personalized approach, that is typical of physiotherapy centers which have long term experience in laser therapy, and specifically with Hilterapia®. While, with this case collection, the authors have demonstrated that the creation of standardized practices dedicated to the most common conditions (muscle contracture, edema, tendinopathies, trauma/contusion, arthrosis and trigger point) can be a useful tool to share the experience of early users to other colleagues which have less familiarity with Hilterapia®. The suggested practices are describing how to integrate the use of the three components of the therapy and have demonstrated that very good results can be obtained without the need of creating new treatment protocols for each single treated patient.

The use of the practice suggestions allows to reach an average of 90% pain decrease, which is an excellent result. It should be underlined that the use of practices provides guidance that allows early users who treat patients not only to guarantee safety of treatment, but also to leverage on the clinical experience of skilled therapists, providing advantages in terms of confidence, time optimization and homogeneity.

## CONCLUSION

The reported clinical experience supports the conclusion that the HIRO TT practice suggestions described in this paper are suitable to be used as general protocol directions for clinical routine practice:

- Contracture
- Edema
- Tendinopathies
- Trauma
- Arthrosis
- Trigger points

Considering that the use of the device

is operator dependent, those practical advices have the aim of providing guidance for making immediately available the beneficial effects of HIRO TT since the first treatments carried out by new users which have little or no experience with the device or with laser therapy.

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