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Hilterapia®: From molecular and cellular effects to clinical studies

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ABSTRACT

Laser therapy has been widely used in many different fields of medicine and has proved to be effective in various pathologic conditions through its anti-inflammatory, anti-edema, and analgesic effects. Despite the richness of literature and the numerous clinical trials that prove the effectiveness of phototherapy, the molecular and cellular mechanisms underlying the therapeutic effects induced by laser emissions of different wavelengths are not completely understood. The study these molecular mechanisms is rather complex due to the different characteristics of the various tissues and body areas (in particular, the different optical properties) and the variety of parameters used in clinical trials, such as wavelength, continuous or pulsed mode, frequency, time of exposure. The aim of this review is to focus on the Nd:YAG laser source used for Hiltherapy and to analyze different studies, both preclinical research and clinical applications, in order to help understand the mechanisms of action of this laser source and the therapeutic effects when it is applied in clinics.

INTRODUCTION

In the course of history, different civilizations have learned that light can have a strong effect on cells and tissues. Starting from Romans, Greeks, and Egyptians, ancient people often used exposure to sun with the aim to obtain positive therapeutical effects. During the 19th century, red light was used to prevent scarring in patients affected by smallpox [1]. Throughout the 20th century, many advances were made with a rapid evolution from arc lamps to modern lasers, which allow us to use high-intensity (when needed), focalized, monochromatic radiation, or to use multiple wavelengths. Since the 70s lasers have been used both in surgery, for tissue ablation, and in many other medical fields, such as physiotherapy, sports medicine, rehabilitation medicine, etc., thanks to the development of laser systems with improved emission modalities.

The effect of laser radiation on biological tissues depends on various parameters, such as wavelength, power, frequency, emission regime (continue or pulsed), exposure time, and, last but not least, tissue optical properties. Proper choice of the treatment parameters allows physicians to control photochemical, photothermal, and photomechanical effects produced by laser irradiation to achieve therapeutic efficacy avoiding or minimizing side effects.

When radiation hits the surface of a biological tissue, about the 3% of it is reflected, due to the change in the refractive index between air and tissue. The remaining radiation propagates within the tissue, where it is partly adsorbed and partly scattered. The absorption of light energy is essential for an effect to occur at cell and tissue level. Light is absorbed by chromophores. They are molecules belonging to the tissues and responsible for tissue properties (e.g. coloring), vary from tissue to tissue, and determine the response of the tissue to the radiation of a given wavelength.

Generally speaking, laser radiation can induce three different kinds of effects in biological tissues: photochemical, photothermal, and photomechanical effects [2]. The photochemical effects occur when the light energy absorbed by a molecule (chromophore) is used for a structural or conformational rearrangement of the molecule, or for a chemical reaction. The photothermal effect takes place when the energy associated with the photons is converted into heat. At tissue level, the results of photothermal interactions depend on the interaction time and the thermal relaxation time of the tissue [3]. The photothermal interactions have been studied under different points of view, since they are crucial in surgery for tissue ablation, while in other medical applications they are useful for inducing moderate peripheral vasodilation, muscle relaxation and enhancement in the rate of biological reactions. Photothermal interactions are also important in laser safety. In non surgical lasers, the temperature of the treated tissues should not exceed 43°C to avoid side effects [3]. In addition to the above effects, the photothermal interactions are also responsible for secondary photomechanical effects. Heating can induce transient modifications of extracellular matrix (ECM) components, such as collagen and other macromolecules, as well as transient fluid dynamics in the ECM, effects that in turn cause mechanical stress on cells, modifying cell morphology and tissue texture. While photochemical effects are mostly induced by Ultraviolet (UV) and Visible (Vis) wavelengths, Near Infrared (NIR) wavelengths, such as that of the Nd:YAG laser emission (1064 nm wavelength), mostly induce photothermal effects and, consequently, photomechanical effects. However, effects of the NIR wavelengths closest to the visible spectrum on mitochondrial enzymes have been reported [4].

In more recent years, lasertherapy has been defined as a form of photobiomodulation (PBM), a generic term to indicate effects of light irradiation on tissues. The term refers to the changes that light (from many different surces) can elicit in biological processes, inducing their stimulation or inibition. PBM is a fashinating way to stimulate and cure tissues pathologies, and new frontiers emerge in a wide range of cellular responses, pain processes, inflammation pathways, and wound healing.

Hilterapia® is a distinguished High Intensity Laser Therapy (HILT) with patented laser pulse (FDA approved in 2003). The laser source is a solid crystal, Nd: YAG, with pulsed, NIR emission at 1064 wavelenght. It falls in the so called "therapeutic window", where the absorption by the major tissue cromophores is lower, allowing laser radiation to penetrate deeper. The emission wavelength (1064 nm), and the related photon associated energy, mostly induces photothermal effects. The pulsed emission is characterized by very high peak power, allowing the propagation of high density photon packages in deep tissues. These properties ensure some advantages. Indeed, high power pulsed radiation cycles permit to penetrate tissues in depth without damaging or disrupting them. In order to analyze photothermal and consequent photomechanical effects, pulse duration and duty cycle need to be considered. The pulse duration (t:on 200 μs) is shorter than the interval between pulses (t:off in the order of ms). Therefore, heat is dissipated without side effects and can diffuse in the targeted tissues producing temperature gradients. The transmitted heat can induce transient modifications of the biological microenvironment [3,5]. These modifications mostly involve the extracellular matrix (ECM), which can translate them into changes in mechanical stress acting on cells, which are connected to ECM via membrane proteins. It has long been known that the ECM performs structural functions, but more recently it has been demonstrated that the ECM has a key role in tissue homeostasis and in the regulation of cell behavior. Thus, the secondary photomechanical effects caused by the Nd:YAG laser can promote ECM remodelling and influence cell-matrix interactions.

In vitro preclinical studies investigated in depth the efficacy of Nd:YAG laser in inducing photothermal and photomechanical effects (see **§ 2)**. Contextually, clinical applications of Hilterapia® showed very good results in osteoarticular and neuromuscuar diseases, with consequent improvement of patient quality of life. Years of daily use by clinicians and many studies published in national and international journals demonstrate the effectiveness of Hilterapia® in rehabilitative medicine and other fields of application (see **§ 3)**. Its first clinical applications were developed in sport traumas and pain therapy, but quickly its effectiveness has been confirmed in degenerative and inflammatory osteoarticular and musculoskeletal diseases.

The aim of this paper is to review both preclinical research and clinical trials on HILT that can help shed light on the mechanisms of action and therapeutic effects, respectively.

2. EFFECTS OF HILTERAPIA® AT CELLULAR AND MOLECULAR LEVEL

It is well-known that mechanical factors are necessary for maintaining tissue homeostasis. Cells are continuously exposed to compressive stress, shear stress, stretching, gravity etc. Consequently, cells reorganize their morphology and reprogram their functions for adapting dynamically to the environmental conditions. Internal and external forces regulate cell shape and many studies have shown that mechanical forces can affect apoptosis, gene expression, protein synthesis, differentiation etc [6].

As reported above, Hilterapia® is based on a high power, pulsed Nd:YAG laser source. Its emission induces in the tissues photothermal effects, which can produce photomechanical effects in the cell microenvironment. Considering the importance of mechanical stimulation on tissue homeostasis, some

in vitro studies on the action mechanisms of Hilterapia® at cellular and molecular level have been devoted to compare the effects of pulsed Nd:YAG emission with those induced by mechanical/gravitational stress due, in particular, to loading/unloading conditions.
In a study of Monici et al. [7], carried out on human mesenchymal stem cells (hMSC), the authors analyzed and compared the effect of Nd-YAG laser radiation with those caused by gravitational factors in order to help understand the molecular mechanisms of hMSC differentiation and the role of mechanical factors in regulating this process. Cell differentiation is the process during which immature (unspecialized) cells take on individual characteristics and reach their mature (specialized) shape and function. During this process, a differentiating cell undergoes an epigenetic reprogramming which causes major changes in cell phenotype and function [8]. In the study, cells were cultured in a Random Positioning Machine or in a hyperfuge to simulate microgravity (unloading conditions) and hypergravity (increase in loading, gravity > 1x*g*), respectively, or irradiated with a pulsed Nd:YAG laser (73 seconds, 1064 nm wavelength, 200 μs pulse duration, 10 Hz repetition rate, 458,65 mJ/cm^2 energy fluence, laser source: Hiro 3, ASA, Arcugnano, Italy) . The results showed that gravitational alterations and photomechanical stress were both effective in inducing specific differentiation patterns in hMSCs. In fact, the expression of Sox9 and Runx2, which are major differentiation markers of chondrogenesis [9] and osteoblastogenesis [10], respectively, was lower than controls in samples exposed to simulated microgravity (unloading conditions), but it was significantly increased in samples exposed to hypergravity (gravity > 1x*g*) and Nd:YAG laser treatment [7]. In addition to this, the genes *MEN1, NF1 and GLI1*, involved in the commitment of hMSCs into the osteoblast lineage [11], bone development and remodelling [12], control of chondrocyte and osteoblast differentiation [13], resulted significantly upregulated after exposure to hypergravity and laser treatment. In contrast, the nuclear receptor PPARγ, the major differentiation marker of adipogenesis [14], significantly increased after exposure to modeled microgravity, whereas it decreased following hypergravity exposure and Nd:YAG laser treatment. The same behaviour was observed in other genes involved in the regulation of adipocyte biological function [15], such as FABP4 [7]. Following the exposure to Nd:YAG laser treatment, an overexpression of *Runx-2* and other genes encoding typical osteoblastogenesis markers, such as *ALP and BMP-2*, was observed also in a later study where hMSC were cultured in 3D scaffold, consisting of decellularized equine bone. This study demonstrated that Nd:YAG laser treatment can stimulate the differentiation towards the osteoblastic lineage and can favor and accelerate the development of three-dimensional bone constructs (data not published). Together with the above changes in expression of major differentiation markers of adipogenesis, chondrogenesis and osteoblastogenesis, the authors found that the exposure to gravitational/photomechanical stress induced cytoskeleton alterations in hMSC [16]. The outcomes of these studies demonstrate that Nd:YAG laser radiation induces photomechanical effects. In fact they are comparable to those induced by hypergravity (gravity > 1x*g*, that is in load increase conditions), while unloading conditions (microgravity) produce opposite effects. It is well known that mechanical stress, such as loading, is of key importance in maintaining the homeostasis of tissues with antigravity functions, such as bone, cartilage and muscle.
It has long been known that the cytoskeleton plays a key role in mechanotrasduction due to its complex and dynamic network of proteins and its ability to sense and mediate cell-cell and cell-matrix interactions [6].

The results of a further study focused on cytoskeleton and extracellular matrix, showed that exposure to Nd:YAG laser treatment induced reorganization of the microtubule network and increase in actin stress fibers [17]. As it is known, stress fibers are involved in the formation of focal adhesions, structures composed by integrins and responsible for cell-matrix interactions [18]. The authors explored also the possibility to utilize pulsed Nd:YAG laser irradiation for modulating the production of extracellular matrix (ECM) molecules by cells of the connective tissues. The ECM is a complex network consisting of numerous proteins (such as collagen and fibronectin), glycoproteins, proteoglycans. It has a key role in providing structural support, but more recently it has been demonstrated that the ECM is also important for cell adhesion, intercellular communication, and cell migration. ECM components are produced and released by cells, but mechanical forces also take part in the process and alterations of such forces can influence the ECM composition [19, 20]. In fact, the increase in mechanical stress acting on cells generally induces an increase in ECM production. By using the above reported laser treatment parameters, authors analyzed the expression of some major ECM

components in different cell types. Collagen II and aggrecan were assessed in chondrocytes while the expression of collagen I and fibronectin was studied in fibroblasts. The results showed that laser treatment significantly increased the ECM molecules in both cell types. Fibronectin, a protein that binds integrins and is involved in different processes, such as cell adhesion, migration, and differentiation, also changed its distribution. Following laser treatment, it assembled in thick and ordered fascicles around fibroblasts instead of the randomly distributed network of fascicles observed in control samples. A significant decrease of metalloproteinases 1 (MMP-1) expression, the major lytic enzyme involved in ECM degradation [21], was found in the treated samples. In addition, the expression of α5β1 integrin, which has a key role in fibronectin matrix assembly, was also evaluated. Immediately after laser treatment, a decrease in α5β1 integrin expression and changes in its distribution on the cell surface were observed in fibroblasts and chondrocytes. This result suggests that laser treatment can induce a reorganization of the fibronectine network associated with a redistribution of its mechanical receptor on the cell membrane. Moreover, given the enhanced expression of aggrecan, which is considered a marker of chondrocyte maturation, authors assayed the expression of Sox 9, a transcription factor involved in chondrocytes differentiation and functions, as the synthesis of ECM molecules. As expected, a significant increase in expression of Sox-9 was found after laser treatment. The findings of this study demonstrated that irradiation by pulsed Nd:YAG laser affects fibroblast and chondrocyte behavior similarly to mechanical stress [17].
Further support to the hypothesis that cell sense pulsed Nd:YAG laser irradiation as a mechanical stress, and respond to it by activation of mechanotransduction machinery, was supplied from the results of another research where the effect of laser treatment (73 seconds, 1064 nm wavelength, 200 µs pulse duration, 10 Hz repetition rate, 458,65 mJ/cm^2 energy fluence) on the production of ECM molecules by fibroblasts and chondrocytes was compared with the effect of loading. Again, the authors found that photomechanical stress induces cytoskeleton remodelling, redistribution of membrane integrins, increase in production of ECM molecules and the effects are similar to those observed in the same cells exposed to cyclic hypergravitational stress (10×g) [22]
A further study was carried out on fibroblasts and endothelial cells, which have a key role in tissue repair process, being the major synthesizers of ECM molecules and cooperating to the formation of new vessels [23]. The cells were exposed to Nd-YAG laser irradiation or to unloading conditions, which can also strongly affect the composition of the ECM because it changes the balance of mechanical forces in the cell microenvironment, and the effects of the two treatments were compared. The results confirmed that in cultured fibroblasts and endothelial cells exposed to Nd:YAG laser treatment there was a reorganization of fibronectin fibrils with the formation of ordered fibronectin fascicles, while unloading induced a strong, but less organized, increase in fibronectin fibrils. Interestingly, the same research revealed that, in sub-confluent endothelial cell cultures, Nd:YAG laser irradiation induced cell spreading and formation of an organized cell monolayer with "paved" appearance, while untreated cells in control samples remained randomly distributed[23]. In conclusion the set of results collected in the above described research demonstrate that cell response to Nd:YAG laser irradiation is very similar to that induced by loading and often opposite to the one produced by unloading, thus suggesting that the biological response occurs via mechanotransduction machinery, as proved by the involvement of cytoskeleton modification and reorganization of integrin receptors.

2.1 SUMMARY

Summarizing, the findings of the studies presented above support the hypothesis that HILT can induce photomechanical effects. Firstly, the data collected from research conducted so far show evidence of cytoskeleton remodelling and changes in the expression level of cytoskeletal proteins, such as tubulin, vimentin and actin [16, 17]. Since it is well known that changes in mechanical stress affect the cytoskeleton structure [20], the results obtained in fibroblasts, chondrocytes and endothelial cells demonstrate that the Nd:YAG laser radiation can modulate mechanical forces acting on cells, thus promoting the reshaping of cytoskeleton. Secondly, all the results presented in this review demonstrate that laser treatment promotes major changes in ECM components, such as collagen, fibronectin and aggrecan. More specifically, the studies reveal that the Nd:YAG laser treatment induces a significant increase in collagen II and aggrecan expression in chondrocytes and a significant increase in collagen I and fibronectin in fibroblasts[17]. Moreover, after laser treatment, there is a reorganization of fibronectin fibrils in different cell lines [23]. Changes in ECM components as well as in their assembly could translate into modifications of cell-ECM interactions and could influence important cell processes, like cell spreading, adhesion and motility. This hypothesis is also supported by the results obtained assessing integrin α5β1, which shows a decreased expression and redistribution after laser treatment [17]. Finally, the outcomes presented above also show that the Nd:YAG laser treatment promotes Sox9 and Runx2 expression in hMSCs, whereas it reduces PPAR-γ expression[7]. Sox9, Runx2 and PPAR-γ are major differentiation markers of chondrogenesis, osteoblastogenesis, and adipogenesis, respectively. Interestingly, according to these studies, the effect of laser treatment on the expression of these markers is comparable to that of hypergravity (loading conditions, $g > 1$), but opposite to that of microgravity (unloading conditions). The fact that laser treatment promotes chondrogenesis and osteoblastogenesis, maturation processes of cells belonging to tissues with antigravitational function, further supports the hypothesis that cell response to pulsed Nd:YAG laser irradiation occurs, at least in part, via mechanotransduction machinery [6]. Even if further studies are needed, the findings of the studies conducted so far are an essential first step to understand the molecular and cellular mechanisms of Hiltherapy.

3.0 HILTERAPIA® CLINICAL RESULTS

Tissues and cellulars finding produced by laser light irradiation through Hilterapia® make it an extremely useful tool in a lot of medical field, in particular in rehabilitative practice. Positive clinical results are found in sport traumas, osteoarthritis and musculoskeletal disorders, wound and chronic ulcers, and in some other struggling conditions.

3.1 SPORT TRAUMAS AND LESIONS

First clinical experiences started in the late 90's, mainly in sportsman affected by lower legs traumas or lesions, in muscles or tendons. In this field main objective is to heal the athlete and reduce the recovery time, allowing a fast return to competitive activity in optimal conditions.

Most sports injuries involve muscles, tendons, ligaments and joints. Injuries are often related to the type of practiced sport, such as epicondilitis in tennis, knee suffering in jump, shoulder problems in volleyball. Moreover acute injuries, such as contusions, distorsions, and muscle strains are common.

In 1997 efficacy of Hilterapia® was described in 97 injured athletes [24] were pain and oedema were reduced with excellent results in 73% of cases, allowing a rapid return to agonistic activity. A wider sport traumatology cases serie was studied in a later study [25]: in 405 cases affected by sports traumatology, clinical and instrumental evaluation was conducted. Improvement was confirmed in 85% of the cases, revealed by subjective and clinical assessment, and confirmed by throught instrumental evaluation.

Studies were also conducted in various selected districts, as pubalgia [26], ankle ligaments [27], patellar tendinopathy [28], muscle strains [29], intersection syndrome [30]. Pubalgia, today defined as "groin pain syndrome", is a specific insertional tendinopathy, a relevant and common complaint in sportsmen, caused by inflammation in tendons of the muscles at the level of the pubis, due to repeated microtrauma in this area. This condition is very frequent in football player, due to typical athletic gesture, and it is of difficult resolution. A rest period is always requested, toghether with phisiotherapy, and often complete recovery time is quite long. In 31 athletes affected by pubalgia treated with Hilterapia® [26], research found a complete and rapid recovery in 14 cases, partial but finally complete recovery in 13, while only 4 athletes needed a longer time to recovery.

In sport ankle lesions recovery time speeding up was revealed [27]: in acute ligamentous lesions same results were obtained in three weeks laser treatment instead of six weeks traditional treatment. Also in patellar tendinopathy in sportsman [28], faster recovery was found compared to C02 laser treated patients, and effective results were reached in muscle lesions in atlethes with 1st degree muscle strain [29].

Thanks to its effectivenes, rapidity of pain relief and recovery fastening, Hilterapia® has been currently used in sport settings from ninety onwards, with public testimonials in football, motorcycle championship, national fencing team, and so on.

Beyond the studies on sports lesions, research applied during years also on degenerative and inflammatory joint disease, and in soft tissues disorders.

3.2 OSTEOARTHRITIS AND MUSCULOSKELETAL DISORDERS

From the first 2000's onwards, Hilterapia® has been studied and applied in the management of all the main osteoarthritis sites, both in degenerative forms and flogistic pathologies, such as Juvenile arthritis or Lupus arthropaty, and in soft tissue pathologies. Hilterapia® clinical effectiveness is sustained by several studies conducted in a wide range of troublesome and common diseases, such as knee osteoarthritis, shoulder affections, low back pain and spinal disorders, osteoporosis, muskuloskeletal pain, as far as inflammatory arthropathy (LES, juvenile arthritis) or emophilic arthropathy.

Knee diseases

A considerable number of international studies in last years focused on lasertherapy in knee OA, because it is a major cause of disability in the elderly, considering its global prevalence and incidence. Cartilage alterations are a main topic in orthopaedic and physiatric research, and PBM therapy is one of the most studied approach between non-surgical and non-pharmacological interventions [31]. Hilterapia® has been studied and confirmed as an optimal resource therapy in this field. Suggestions in cartilage regeneration were found [32,33], and clinical results like reductions in knee pain, increases in ROM, and increased functionality were consistently observed: VAS, Womac Score, ROM goniometry improvement were reported [34-43].

A randomized controlled clinical trial [35] compared the effects of Hilterapia® vs viscosupplentation in 41 patients suffering from symptomatic knee OA. Positive results of the two type of treatment were analogous: improvement was found in Womac and Lequesne Scale at the end of the treatment and at 4 months follow-up, with Hilterapia® being less invasive and safer than articular infiltrations. Analogous study was conducted later [36], comparing two treatment protocols, only differing in the number of sessions (10 sessions or 5 Hilterapia® sessions). Hilterapia® was found to produce a rapid antalgic effect, in the very first sessions. Furthermore the duration of HILT effects seemed to be dose-related, because the shorter protocol showed a rapid pain relieve, but a tendency to regression. A clinical investigation was conducted [37] in 30 Knee OA patients, comparing Hilterapia®, LLLT and ultrasound therapy results. In this study Hilterapia® had a more analgesic effect compared to LLLT e US, toghether with functional test improvement (walking distance and squat), and a better patient's satisfaction index.

Many other experiences confirmed the efficacy and safety of Hilterapia® in painfull knee [34-43], because knee pain is approachable according to the clinical phase, in a periarticular soft tissues approach or with the objective of treating intraarticular space, benefiting from regenerative properties of the device. Results of LLLT and HILT treatment, in combination with exercises were compared in knee OA patients [41]: Hilterapia® resulted more effective (VAS and WOMAC Scale) than LLLT treatment. Efficacy of pulsed Nd:YAG laser, Hilterapia®, in the treatment of patients with knee osteoarthritis was evaluated also in another study [42]. The study included 50 patients with diagnosed grade II to III arthrosis, were treated, and conclusions were that HILT significantly reduced pain, stiffness and problems with normal daily activities. Investigation of the effects of pulsed Nd:YAG laser plus glucosamine/chondroitin sulfate in patients with knee osteoarthritis was carried out: the addition of HILT determined a plus in patients improvement. In 96 gonarthrosis patients HILT enabled prompt analgesic effects in KOA treatment [43].

All these researches showed high efficacy and safety in KOA patients treatment, inside rehabilitative settings.

Shoulder diseases

Acute or persistent Shoulder pain is a very common condition, associated with high social cost and patient burden. It is mostly due to tendon inflammation (bursitis or tendinitis), glenohumeral osteoarthritis, or rotator cuff tendon tear. So painful shoulder is a very common complaint, increasing after the age of 50 especially in working populations. In this affection a lot of studies found efficacy and safety of Hilterapia®, from the first reported studies [44-50], till nowadays [51-53]. Painful shoulder syndromes were several times investigated. Subacromial Impingement Syndrome (SAIS) was studied in some forms: Hilterapia® showed its advantage versus ultrasound (US) therapy in the treatment of SAIS [53]: participants diagnosed with SAIS showed greater reduction in pain and improvement in articular movement, functionality and muscle strength of the affected shoulder after 10 treatment sessions of HILT than did participants receiving US therapy over a period of 2 consecutive weeks. Hilterapia® and manual therapy were found to be more effective than other interventions in minimizing pain and disability and increasing ROM in patients with SAIS. The effect of HILT is confirmed in a study [49] on seventy patients with SAIS, evaluated with SPADI Scale and subscales. Forty patients who were diagnosed with 1 - 2 stage impingement syndrome pain were treated and analized [51]: post-program comparation revealed a statistically significant reduction in ultrasonography dimension of supraspinatus and VAS and significant increase in ROM of shoulder flexion and abduction, in favour to the treated group with Hilterapia®.

It's possible to conclude that high level laser therapy produces great improvement in shoulder mobility in impingement syndrome. Improvement is found in the short and long term.

Spinal disorders

Neck and Low back pain treatment remains a struggling argument in

medical literature, and international guidelines don't totally agree [54]. Back pain represent a main topic of rehabilitative treatmens, and the various proposed protocols generally combine physiotherapy with instrumental options.
Almost 20 years of clinical practice and demonstrations, support the efficacy of HILT trough Hilterapia® in spinal pain of various origin. Special efficacy was reported in several studies on low-back pain [55-63]: in mechanical LBP wheter acute o chronic form [61-63], in LBP from disck erniation [55], in sciatic nerve radiculopaty [56, 57] pain decrease and improvement in functional tasks were reported. Its efficacy, in terms of VAS, and disability scores (Roland Disability Questionnaire and Modified Oswestry Disability Questionnaire) is reported in several researches [60-63], were lasertherapy is combined with exercises and compared with other standard physical therapies.
Also in neck pain Hilterapia® showed high efficacy, in combination and compared with other classical intervents. It was compared with ultrasound and trancutaneous electrical stimulation in 84 cervical spondilosis patients [64]: HILT plus exercise was more effective than US/TENS plus exercise. Other studies report efficacy of Hilterapia® in chronic neck syndrome [65], cervical myofascial pain syndrome [66], in cervical radiculopathy, [67], in cervical spondilosis [68].
A recent systematic review and meta-analysis in the treatment of spinal disorders confirmed the efficacy of this type HILT treatment [69]. Osteoporosis, which is a main source of vertebral pain, also improved with Hilterapia® [70-72].
Analogous positive results were found in soft tissues and musculoskeletal disorders [73-82], such as epycondilitis [73, 74], plantar fascitis [75,76], carpal tunnel syndrome [78]. Particularly severe tendon and ligament injiuries (triceps tendon rupture, Achilles tendon partial rupture or fibrillar degeneration, subachillar bursitis and partial abruption of Achilles tendon insertion, medial collateral ligament partial rupture, lateral and medial meniscus and MCL partial rupture) were assessed by musculoskeletal examination, thermography, musculoskeletal sonography and VAS [79, 80]. Results showed promoting repair in tendon and ligament structures in all cases, reducing pain in all cases and favouring restoration of the function in all cases. An interesting case report on Tieze Syndrome patient was conducted [77]: Hilterapia® allowed managing severe pain not responding to drugs treatment. The result obtained in 9 sessions was a complete elimination of pain, which persisted at 40 days follow up, and the patient returned to her normal activities.

3.3 REGENERATIVE TREATMENT

Hilterapia® efficacy in regenerative treatments is mainly attributable to its photomechanical effect. In fact a distinguishing characteristic of Hilterapia® is its capability to produce photomechanical effects on the treated tissues. Entity of such effect is directly proportional to laser emission intensity, and inversely proportional to impulse duration. Hilterapia® impulse presents ideal features to produce such stimulation, that leads to cellular cytoskeleton reorganization in endothelial, mesenchimal and connective cells, and promote extra-cellular matrix production, similarly to mechanical stimulus. It induces connective cells differentiation and endothelial layers formation, thus promoting tissue repair processes. The efficacy of Hilterapia® in stimulating tissue regeneration and healing has been demonstrated in wound healing [83], chronic ulcers [84], diabetic [85] or neurogenic ones [86], which are generally non healing or long lasting and disabling conditions. Although regenerative and proliferiative effect is evident in skin lesions, regenerative properties are of main relevance also in rehabilitative treatment, favouring healing of non directly visible soft tissues lesions (tendons, burses, etc), whether of degenerative or traumatic origin, and stimulating cartilage repair.

3.4 OTHER CONDITIONS

Inter alia, Hilterapia® showed positive results in many other rehabilitative domain such as balance [87], post mastectomy pain syndrome [88], postburn pruritus [89], linphoedema [90], haemophilic arthropaty [91,92], bells palsy [93], pain management [94], confirming wide and various direct and indirect effects.
In all the cited studies a very high level of safety was reported, considering that it was used also in hemophilic arthropatic patients without side effects.

3.5 SOME PRACTICE DETAILS

From a practical point of view Hilterapia® devices are characterized by pre-imposted programs, togheter with personalized possibilities from the operator. This fact allows a customized treatment. Laser power emission and erogation modality consent a lot of approaches and time saving, for the operator and for the patients. Its particularity are intensity and depth of treatment (some centimeters) which allows healing of deeper structures. Treatment is typically distributed in three phases: the first phase is directed to control muscle contracture in periarticular group muscles

and relax trigger points. The second phase is more specifically addressed to the suffering tissue (es tendon, or articular components, oedema, etc), even through optical windows. Third and last phase is direct to pain irradiation areas. The first session treatment leads to an immediate improvement in pain level reduction, up of 50%. A few laser sessions obtain further pain control, which increases as the sessions continue. This fact makes it possible to start mobilization, while antiinflammatory and restorative effects occurs, so implementing and stabilizing results over the time, in a virtuous circle. Mean session number reccomended is 8-10, carried out daily or every other day. According to cited literature Hilterapia® is an extremely flexible technology, because it allows modulation in intensity, frequency and energy according to the clinical situation and the type of pathology, both in acute and chronic phase.
Adding co-intervention is usual in clinical rehabilitative practice, as combined interventions generally obtain better functional results. Hilterapia® is easily and safely combined with ultrasounds, TENS, ECSWT, and other common physioterapy devices.This is just a summary of ascertained Hilterapia® clinical effects on musculoskeletal system diseases. In this review we outlined the researches of main interest, were Hilterapia® showed interesting results in various affections of rehabilitative concern. Positive influence of adding Hilterapia® to physiotherapy interventions in musculoskeletal pain management is well recognized.

3.6 SUMMARY

Hilterapia® is a main tool in rehabilitative settings as part of an integrated rehabilitation program, for pain management and tissues healing. Beyond the typical effects of LLLT, its specific advantages are:
Transfer in depth of higher energy amount, which enables deep tissues treatment. A strong photomechanical effect, which allows specific tissues reactions A very rapid effect on pain, the basis for carrying out mobilization and exercises. Reduction of treatment times, much appreciated in patients and operators, and a long lasting effect.

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New Treatment for Chronic Heel Pain in Plantar Fasciitis

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INTRODUCTION

Plantar fasciitis is a painful condition of the foot. It is defined as an inflammation of the plantar fascia, the fibrous envelope of the tendon that forms the arch of the foot (from the Latin "fascia"). The role of the plantar fascia is to support and protect the tendon on the sole of the foot.

Plantar fasciitis is one of the most common causes involving pain at the base of the heel. In the course of life, it affects up to 10% of the population. It usually lasts for at least 6 months, rarely reaching a year. The clinical course for most patients is positive, about 80% report a resolution of symptoms within 12 months. [Martin RL et al.]

Plantar fasciitis mostly affects the population between 40 and 60 years of age, the women and obese subjects.

Plantar fasciitis mostly affects the women, obese subjects, athletes – especially runners and population between 40 and 60 years of age.

Among musculoskeletal injuries related to running, the incidence of plantar fasciitis varies between 4.5% and 10%, with a prevalence between 5.2% and 17.5%. [Lopes AD et al.]. Sudden increase in mileage out of proportion to training, incorrect running posture, wrong choice of running shoes, running on too hard ground, are all possible causes of plantar fasciitis development.

The precise mechanism of onset of plantar fasciitis is still being studied, as the research conducted so far reports conflicting data. Experts agree in considering this condition as the result of excessive stress on the plantar fascia which, if subjected to repeated stress and microtrauma over time, degenerates and becomes painful.

The diagnosis of plantar fasciitis can be made through the only physical examination; however, medical doctors (in alternative physicians) may also order imaging studies to clear up any doubts and to rule out other possible causes of heel pain.

Plantar fasciitis takes several months (6 to 12) for complete recovery from pain symptoms that, interfering with daily routine, could impair life quality. Among the therapies planned to solve this condition, there are: the pharmacological approach, aimed at affecting the symptoms of plantar fasciitis by administering non-steroidal anti-inflammatory drugs and corticosteroids; the "strengthening" approach with stretching and strengthening exercises and the use of specialized devices (splints, orthotics); the surgical approach and therapies based on the use of physical agents like extracorporeal shockwaves therapy (ESWT) and laser therapy.

Shock waves are pulsed acoustic waves that dissipate mechanical energy at the interface of two substances with different acoustic impedance. Such therapy has demonstrated good results in the treatment of patient affected by plantar fasciitis [Li et al.] but it is not free of collateral effects.

Roerdink et al. in their systematic-review on the complication of ESWT in plantar fasciitis, found that the 11.6% of the patients reported pain during the treatment. Dysesthesia, swelling, ecchymosis and/or petechiae, severe headache, bruising, throbbing sensation and temporary pain after treatment, <1 week from the treatment session end, were also been noticed.

Laser therapy has been demonstrated to provide many beneficial effects through photochemical, photothermal and photomechanical interaction with the tissue.

Low-level laser therapy (LLLT) by class 3B lasers with Power <500 mW, in a recent systematic review [Guimarães et al.] demonstrated to be effective in the treatment of plantar fasciitis, reducing pain of 2.2 on a 0–10 pain scale and providing an average improvement in pain of 40%. Moreover, compared to extracorporeal shock wave therapy, LLLT resulted equivalent in reducing pain intensity in the short term.

In the last years High-intensity laser therapy (HILT) by class 4 laser source with power > 500 mW, has gained importance in the treatment of musculoskeletal disorders and sports injuries [Brown et al., Dundar et al.]. HILT has been recognized to be a safe, non-invasive and non-painful therapy.

Clinical evidence on the effects of HILT in combination with other phys-

ical therapies are limited despite treating patients with several therapies during the same treatment session and/or in succession, is becoming part of common practice.
Akkurt et al. evaluated the effects of HILT in combination with insole versus insole alone, in patients affected by chronic plantar fasciitis and found that the combined therapy was more effective than the sole insole in terms of pain and quality of life.
The purpose of this study was to evaluate the performance of ESWT, HILT and their combination, in patients with chronic heel pain, caused by plantar fasciitis, in terms of pain relief.

We hypothesize that the use of ESWT and HILT combined together in succession, during the same session treatment, could act synergically and lead more benefits in terms of: less invasiveness and pain symptoms after the treatment and higher antalgic, anti-inflammatory, anti-oedema, reparative and regenerative effects on deep structure.

MATERIALS AND METHODS

This prospective, randomized, single center trial was conducted at the Yekaterinburg Medical Research Center for Prophylaxis and Health Protection in Industrial Workers of Yekaterinburg, Russia.
Data were collected from a group of 40 consecutive patients aged between 40-50 years, affected by chronic plantar fasciitis, lasting over 3 months, without any remission of signs and symptoms, pain over 4 on visual analogue scale (VAS).
The diagnosis was made through physical examination; the enthesopathy was evaluated by ultrasonic indicators: thickness of the plantar fascia, homogeneity, swelling, calcification, neovascularization. Figure 1.
No other inclusion or exclusion criteria have been used. The population was randomly divided in four groups: Group 1 (n=10) received placebo; Group 2 (n=10) was treated with HILT; Group 3 (n=10) was treated with ESWT; Group 4 (n=10) received ESWT+HILT combined.
Change of pain intensity from baseline to the end of the treatment sessions, as reported by the patients on a Visual Analogue Scale (VAS), in the four groups of treatment, were calculated and compared statistically. The VAS scores were collected before each treatment session.
Patient randomized in Group 4 received initially the treatment with ESWT and immediately after a treatment with HILT. This choice was made because HILT could alleviate the painful temporary sensation some patients feel after a ESWT session. Figure 2.
At one month, after the onset of the treatment cycle, the patients underwent to an ultrasound exam to evaluate changes of the swelling and plantar fascia structure.

HILT PROTOCOL

Pulsed high power laser (Nd:YAG, λ=1064nm, Hiro 3, ASA Laser, Arcugnano, Italy) was applied as 10 sessions performed daily in two weeks. All treatments were performed according to instructions in operating manual. Each session lasted 10-15 minutes and was divided in three phases: fast manual scanning, trigger point treatments and slow manual scanning. Each phase was done applying a fluency increasing / frequency decreasing emissions. The predefined plantar fasciitis settings were: fluency of 970-1080-1170 mJ/cm^2, frequency of 30-20-10 Hz, total energy of 1000-1250-1500J.

ESWT PROTOCOL

For ESWT therapy was used a Salus Optimus Pro (Madisson, s.r.o.), with radial shock waves, energy density of 2.5-3 bar, frequency set to 10-13Hz, and predefined plantar fasciitis treatment mode. All treatments were performed according to instructions in operating manual. Each patient received 5 treatments in 2 weeks: 3 treatments the first week and 2 the second one.

RESULTS

At baseline, the patients in the four different groups were comparable by gender, age and severity of clinical manifestations.
Average pain intensity in the population under examination at baseline was 7.1±1.9 on a 0-10 scale.
At the end of the treatment cycle the patients who received HILT (Group 2) or HILT+ESWT (Group 4) reported a significant improvement of pain ($p \le 0.05$). Patients treated with ESWT alone (Group 3) reported a decrease of pain on VAS scale but not significant; while, placebo group showed no improvement. All the results are showed in Figure 3 and Table 1.

In group 4, VAS scores before and after treatment were 7.1±1.2 and 2.1±1.1 respectively; already after a short period of time, 4.3±1.2 days, was achieved the greater drop in pain intensity. Ultrasounds performed at follow-up, one month after the onset of the treatment cycle, showed a reduced swelling and signs of structure repair in plantar fascia. Figure 4.

Patient of group 2, HILT monotherapy, significantly decreased pain in 8-10 days since the onset of the therapy; the VAS score before and at the end of the treatment cycle were 7.2±2.1 and 3.2±1.8 respectively. At follow-up the ultrasound exam presented a reduced swelling in plantar fascia. Figure 4.
In the group 3, the effects of ESWT emerged in over a 14 days' period, in correspondence of the last treatment. The VAS score before treat-

ment was 6.9±2.1, after treatment was 4.3±2.6. At follow-up visit no ultrasound changes were seen. No adverse events or side effects were recorded during the entire curse of the study.

DISCUSSION

In this prospective study, patient with chronic plantar fasciitis, were treated with ESWT, HILT or with a combination of the two therapies and their effects on pain were evaluated.

The results showed a significant reduction of pain in patients treated with high intensity laser therapy alone or in combination with the external shockwave therapy. In the group of patients treated with two therapies in combination, it was obtained the greatest reduction in pain in the shortest period of time.

These results are in line with those found by Takla et al. where 120 patients with chronic plantar fasciitis received either ESWT with photobiomodulation therapy (PBMT), ESWT (once a week), PBMT (three times a week), or sham-PBMT (three times a week) for three consecutive weeks. PBMT was provided with low level GaAlAs laser.

Both ESWT and PBMT showed an increase in pressure pain threshold values, a decrease of pain and an increase of functional ability. As we found, the application of PBMT in combination with ESWT resulted to be superior over ESWT and PBMT alone.

This could be related to a smaller number of treatment sessions and a relative shorter period before the evaluation of the therapy effects, 2 weeks instead of 3 weeks.

Our results sustain the hypothesis that HILT and ESWT in combination could lead to therapeutic mechanisms that potentiate each other, and that act synergistically.The shockwaves initiate a number of non-specific responses at tissue level both in correspondence of the front wave and at damping part of the wave. The front wave initiates the cleavage of chemical bonds within the components of cell membranes and alters the mechanical properties of cell membranes. These changes occur only in the damaged cells and cause their cytolysis (osmotic lysis).

The damping part of the shockwave stimulates metabolism, regeneration and immune processes within the damaged tissues. Resulting from the removal of dead cells and cellular debris by the macrophages and the edema resolution, the compression of nerve fibers and nerve receptors decreases. This ultimately relieves the pain.

The high intensity laser therapy uses a source with a low tissue absorption coefficient (Nd: YAG) with the emission of impulses. The patented pulses, generated by the Hiro 3 device, are characterized by very high peak powers (1-3 kW), high energy content (150-130 mJ), short duration (120-150 μs), low frequency and duty cycle in the order of 0.1%.

The characteristics that differentiate the HILT from traditional therapies are: the wavelength - 1064nm, high peak power and short pulse duration. This can favorite the photomechanical and biological effects on the tissue [Monici et al.]

In this study HILT therapy demonstrated to be effective both alone and in combination with ESWT.

In particular, in this second scenario, it seems that the HILT administrated immediately after ESWT, could potentiate the positive effects emerging at the damping area, producing a greater and quicker improvement in pain respect to a monotherapy without any side effects.

CONCLUSIONS

HILT and ESWT are usually applied in physical therapy department alone or in combination; when applied together, showed significantly better results in managing chronic heel pain in patients with chronic plantar fasciitis, with regard to both reducing pain and structural repair of plantar fascia.

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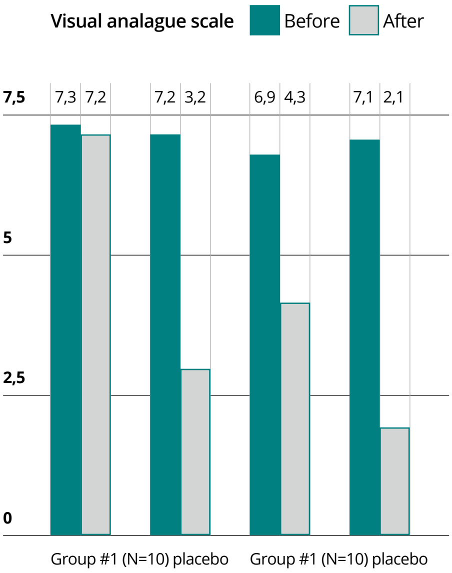

	VISUAL ANALOGUE SCALE (CM) MEAN (STD)			
	Baseline	**End of Treatment**	**ΔVAS**	**p-value**
GROUP 1 - PLACEBO	7.3	7.2	0.1	NS
GROUP 2 - HILT	7.2 (2.1)	3.2 (1.8)	4	p<0.005
OUP 3 - ESWT	6.9 (2.1)	4.3 (2.6)	2.6	NS
GROUP 4 - HILT+ESWT	7.1 (1.2)	2.1 (1.1)	5	p<0.005

Table 1. VAS score values before and after the treatment

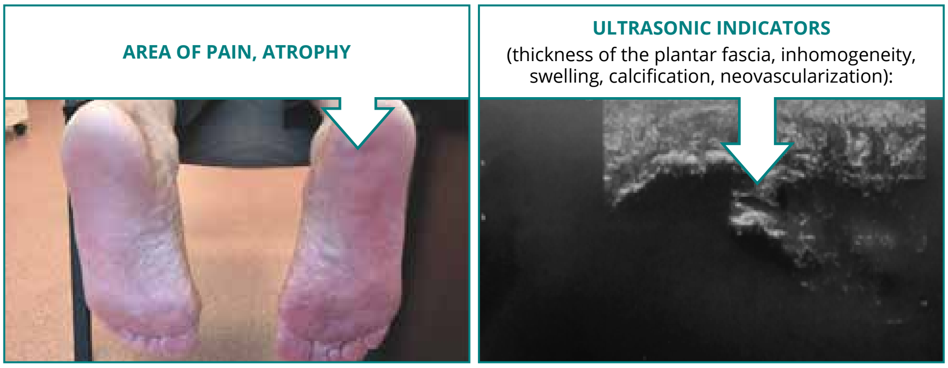

Fig 2. Group 4 – treatment with ESWT and HILT during the same session.

Fig 3. Evaluation of the Visual Analogue Scale in the different groups before and after the treatment cycle sessions.

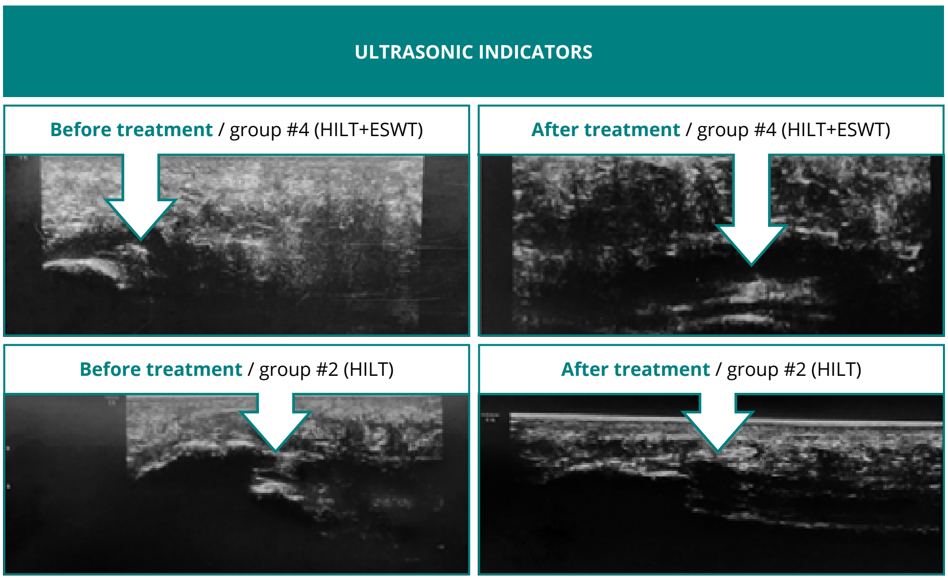

Fig 4. Ultrasound evaluation of the effects of HILT therapy alone or in combination with ESWT at follow-up.

Use of Acupuncture in combination with MLS® Laser Therapy in aged dogs with osteoarthritis: three clinical cases

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INTRODUCTION

Osteoarthritis in dogs is a slowly progressive inflammatory chronic disease, characterized by degeneration of the cartilage, hypertrophy of margins of the bones and changes in the synovial membrane. These alterations can cause decreased flexibility, lameness, stiffness and pain. Conventional treatments of osteoarthritis involve nonsteroidal anti-inflammatory drugs, corticosteroids, chondroprotectors and other complementary medications (i.e. gabapentin and amantadine). Pain management is the main goal of medical treatments, in order to improve the quality of life in old patients. Chronic conventional treatments could affect the patient health condition. Alternative therapies, such as acupuncture and MLS® laser therapy, are considered good options for the treatment of osteoarthritis in these patients.
Multiwave Locked System (MLS®) laser therapy has been clinically advised for treatment of several pathologies, including neuropathic pain and musculoskeletal diseases. It involves the use of two different and synchronized emissions. The average power of the device is 1.1 W with pulsed emission of 25 W. Studies demonstrated that MLS® therapy, in combination with pharmacological therapies, is able to improve general clinical condition of dogs affected of osteoarthritis.
Acupuncture belongs to Traditional Chinese Medicine (TMC) and consists in stimulating specific points on the surface of the body (acupoints). The mechanism of action of acupuncture is complex and includes local mechanical effects and the modulation of peripheral and central nervous system pain signaling pathways. Acupuncture has been shown to activate afferent nerve fibers and regulate signaling molecules, such as endogenous opioids, to mitigate pain.
This article is intended to share a previous experience in using MLS® laser therapy in combination with acupuncture in the treatment of pain of three aged dogs with osteoarthritis. The purpose was to manage pain reducing or stopping pharmacological therapies and to improve physical and psychological quality of life of these dogs.

CLINICAL CASES

Case #1

Slam, 16 Y, inctact, male, Golden Retriever. Main problems: difficulty getting up, right hindlimb lameness, degenerative joint disease of metacarpo-phalangeal joints and generalized hypomyotrophy.
Actual treatment: grapiprant.
According to TMC: Kidney Qi Deficiency and Spleen Qi Deficiency.
Acupoints: VG20 (*Bai-hui*), VG17 (*Nao-hu*), BL20 (*Pi-shu*), BL21 (*Wei-shu*), BL23 (Shen-shu), ST36 (*Hou-san-li*) bilateral, BL40 (Wei-zhong) bilateral, GB34 (Yang-ling-quan) bilateral, KD1 (*Hou-quan*) bilateral, *Bai-hui*, *Liu-feng* of the thoracic limbs. MLS® laser therapy: point-to-point mode (six points) with 292 Hz frequency and fluence 4.06 J/cm^2 according to "arthrosis" program on metacarpo-phalangeal area of both limbs. Treatment sessions: once a week for eleven treatments.
Outcome: after two weekly sessions, Slam was able to walk for about 20 minutes in the courtyard. For that reason, the grapiprant administration has been stopped. The patient was still uncomfortable in getting up. After the fourth session, owner claimed an overall improvement in mobility. For family reasons, the owner decided to stop further sessions for about one month. During this period, the owner reported a progressive

worsening of the previously described clinical signs. She decided to treat Slam with corticosteroids under advice of her vet. After that the owner contacted us to re-start the acupuncture and laser therapy. The patient showed an overall improvement in mobility and pain relief without any medication after at least seven sessions. Difficulty getting up has never been completely resolve.

Case #2

Iron, 15 Y neutered male, mix Labrador breed dog. Main problems: degenerative joint disease of the left elbow, suspected left cranial cruciate ligament rupture and painful at the lumbar region palpation. According to TCM: Bony *BI* Syndrome; Kidney Yin and Qi Deficiency. Acupoints: VG20 (*Bai-hui*), BL11 (Da-zhu), BL23 (Shen-shu), BL26(*Guan-yuan-shu*), *Bai-hui, Shen-shu*, *shen-peng,* KD3 (*Tai-xi*) bilateral, KD6 (*Zhao-hai*) bilateral, SP6 (*San-yin-jiao*) right side, SP9 (*Yin-ling-quan*) right side, ST36 (*Hou-san-li*) right side, LI10 (*Qian-san-li*) left side, LI11 (*Qu-chi*) left side, SI8 (*Xiao-hai*) left side.

MLS® laser therapy: the treatment was carried out on points (six points) covering the whole left stifle joint with 18 Hz of frequency and 4.06 J/cm^2 according to "acute inflammation" program for the first two sessions, then point to point mode (six points) with 36 Hz of frequency and 4.01 J/cm^2 according to "chronic inflammation" for the last eight sessions (Fig.1).

For the left elbow, the treatment was carried out on points (six point) covering the entire joint with 292 Hz frequency and 4.06 J/cm^2 according to "arthrosis" program. A muscle scan was performed on the lumbar region with 36 Hz of frequency and 4.03 J/cm^2 according to "back pain" program. The intensity was reduced to 75% due to the dark fur.

Treatment sessions: once a week for the first five treatments and once every two weeks for the last five treatments Outcome: Iron is initially treated with acupuncture and laser once a week for five treatments and then every two weeks for the last five treatments. The owner reported an improvement after the second session; Iron started to walk better.

His lameness has never been completely resolved but he had a good relief of pain.

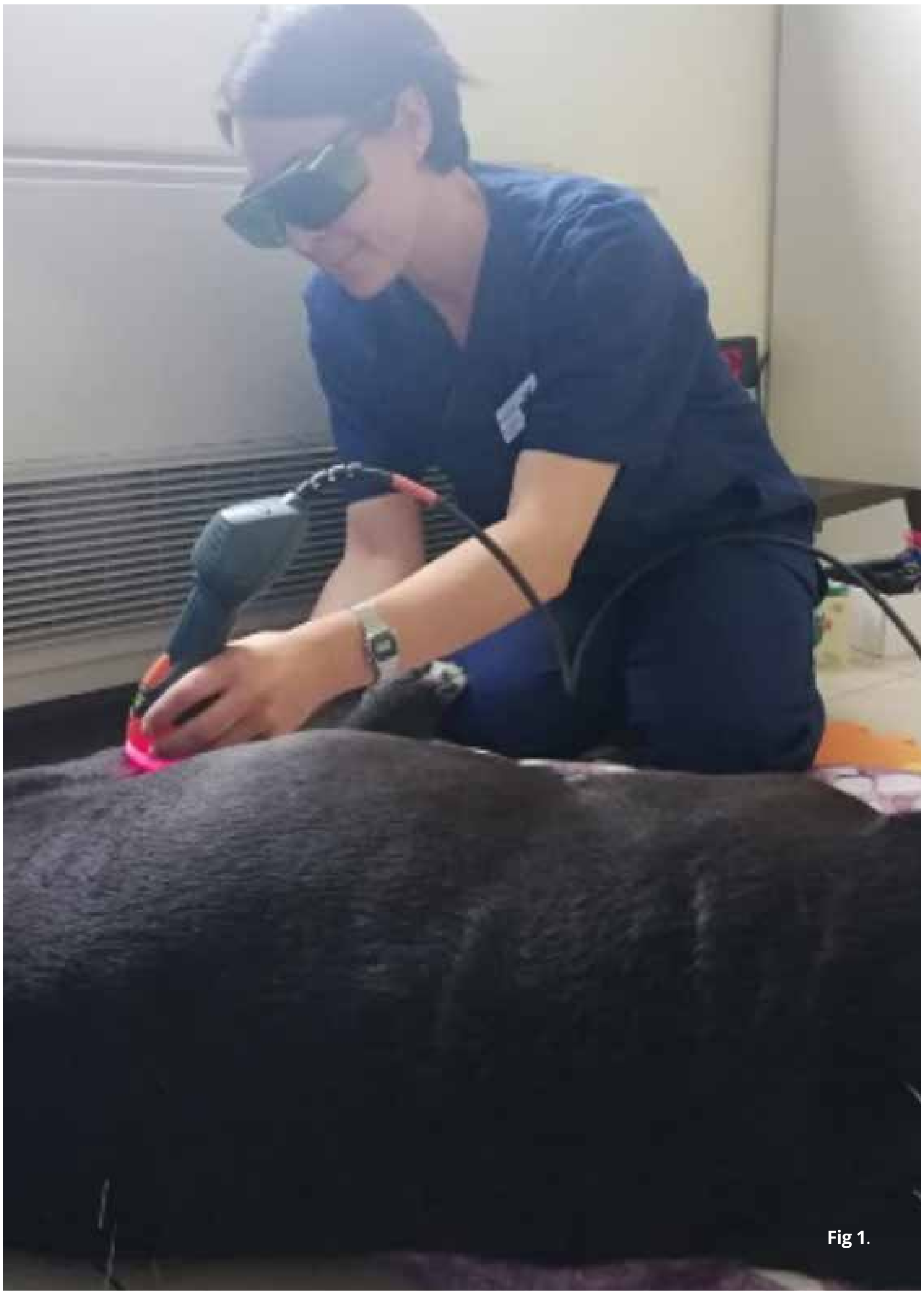
Fig 1.

Case #3

Calvin, neutered male Belgian Sheperd, 13 years old. Main problems: multifocal intervertebral disk herniation (L1-L7) and severe right sided hip degenerative joint disease associated with ipsilateral regional hypomyotrophy.

He is under robenacoxib and gabapentin because of a traumatic event during grooming three weeks before. According to TCM: Bony *BI* Syndrome; Kidney Yin and Qi Deficiency.

Acupoints: VG20 (*Bai-hui*), BL11 (Dazhu), BL23 (Shen-shu), BL26 (*Guan-yuan-shu*), *Bai-hui*, KD6 (*Zhao-hai*) bilateral, SP6 (*San-yin-jiao*) bilateral, ST36 (*Hou-san-li*), right side, LIV3 (*Tai-chong*) right side, LIV11 (*Yin-lian*) right side, GB29 (*Lu-liao*) right side, BL54 (*Ba-shan*) right side, GB30 (*Huan-tiao*) right side. MLS® laser therapy: the treatment was carried out on points (six points) covering the right hip joint with 292 Hz frequency and fluence 4.06 J/cm^2 according to "arthrosis" program (Fig.2).

A scan phase on the lumbar region was performed with 36 Hz of frequency and 4.03 J/cm^2 according to "back pain" program. The intensity was reduced to 75% due to the dark fur. Treatment sessions: once a week for four treatments.

Outcome: the owner reported a sudden improvement in mobility after one treatment and returned to normal after the third treatment. Calvin had a general improvement in mobility and started to jump again; for that reason, we decided to stop all medications.

A slight right sided hindlimb stiffness was still noticed, with no apparent pain at extension of the hip.

DISCUSSIONS

Acupuncture and MLS® laser therapy have proved to be useful in the treatment of chronic musculoskeletal conditions such as osteoarthritis in older dogs. The contribution of acupuncture to pain control includes muscle relaxation and improvement in oxygen and nutrient distribution to the affected area. In a veterinary previous study, MLS® laser therapy demonstrated the same efficacy in pain and inflammation control as drug therapy, but without its side effect, in dogs with osteoarthritis. Therefore, the use of a multimodal therapeutic approach may reduce doses of conventional

Fig 2.

analgesics and their adverse effects, an important concept in geriatric patients. General owner's subjective impressions were that dogs treated with acupuncture and laser therapy were more able to walk and had less exercise intolerance.
Stiffness and rigidity were non completely resolved but an overall improvement in quality of life, both physically and psychologically, was noticed. Due to the limited sample size and the absence of validated pain scales, such as Helsinki Chronic Pain Index, during follow up, this study represents a preliminary investigation.

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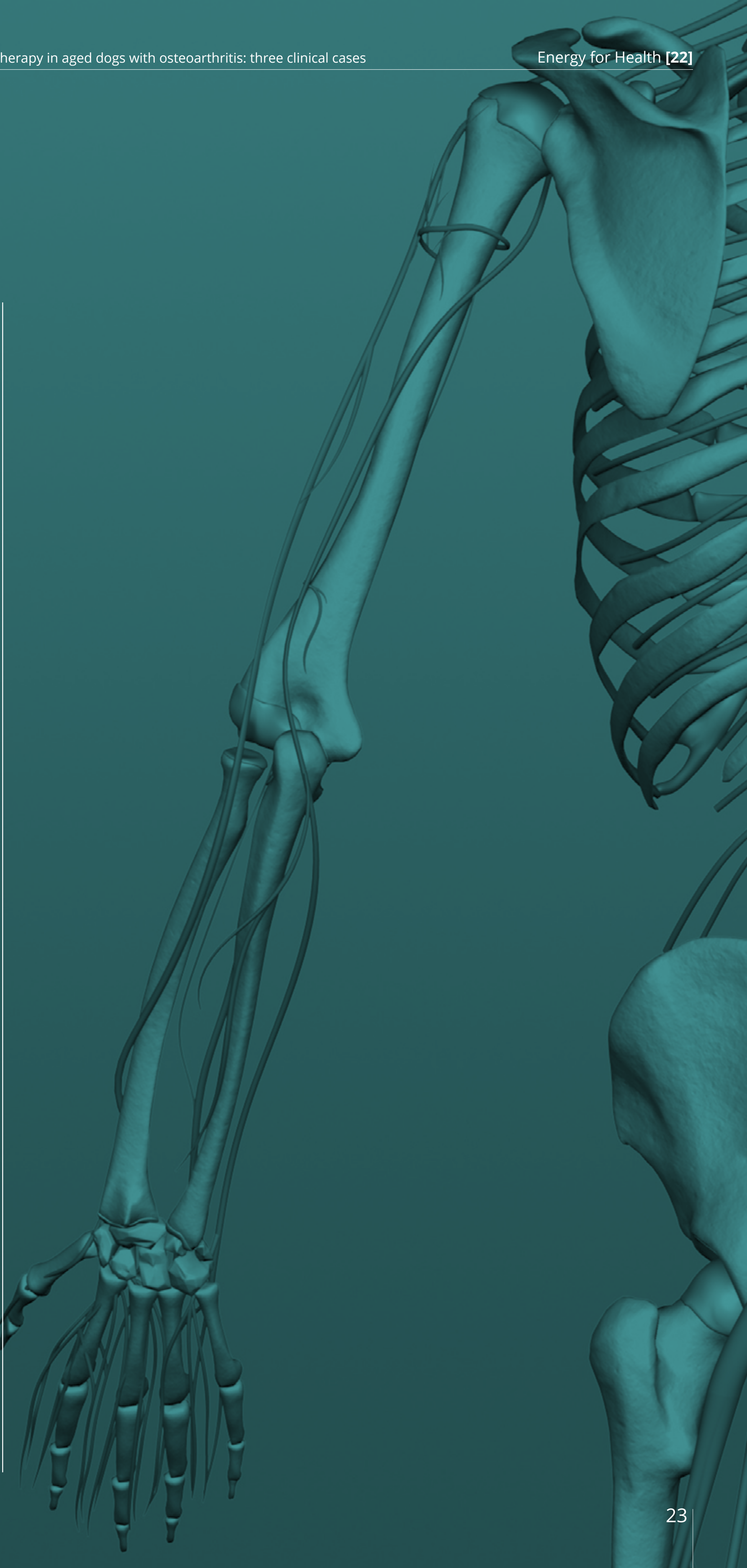

Key words: pets, dog, cat, brachial plexus avulsion, neurologic disease, physiotherapy, conservative treatment, autonomous movement

Conservative physiotherapy treatment in 4 patients with brachial plexus avulsion

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ABSTRACT

The avulsion of the brachial plexus is a pathology often resulting from trauma and quite frequent in the clinic of small animals. In addition to drug therapy with prednisone, it is important to start physiotherapy immediately to counteract neurogenic atrophy.

There is no surgical treatment and the alternative to a physiotherapeutic intervention is represented by the amputation of the involved limb, in order to avoid self-trauma. Currently, an integrated physiotherapeutic intervention is applied, consisting in appropriate exercise, laser therapy and diathermy. In this work, the outcome of conservative treatment was evaluated for 4 subjects suffering from avulsion of the brachial plexus, which arrived at the "Livorno Veterinary Physiotherapy" Clinic.

Different parameters were studied and the pre- and post-conservative physiotherapy clinic compared. The 50% had a positive outcome with recovery of the autonomous movement; the remaining patients did not have clinical recovery, resulting in a permanent loss of autonomy.

The present study highlighted that an important variable to treatment success is the time interval from diagnosis to the start of therapy: the best results were obtained for shorter waiting times.

INTRODUCTION

Brachial plexus avulsions are divided into cranial, caudal and total. The cranial one affects the C6 - C7 roots. There is modest atrophy of the supraspinatus and infraspinatus muscles, reduced arm extension and elbow flexion but there is good elbow extension. The caudal avulsion affects the roots C8 - T1 and T2. The symptoms are more important and the animal is unable to support the limb that is held with the shoulder and elbow flexed. Sometimes there is transient damage to the spinal cord with consequent involvement of the ascending and descending fibers relating to the ipsilateral hind limb, therefore in the first phase it is possible to find postural neurological deficits and posterior ipsilateral MNS syndrome. The total avulsions are a sum of the two previous ones, the limb is dragged hemiplegic and the prognosis is poor because the chances of reinnervation are minimal (1, 2). Diagnosis is achieved by clinical examination, electromyography, CT and MRI. The treatment in this case is exclusively conservative, trying to protect the limb from further injuries, self-trauma, muscle contractures and subjecting the patient to rehabilitation. In addition to drug therapy with prednisone, it is important to start physiotherapy immediately to counteract neurogenic atrophy. There is no surgical treatment (3). For this pathology the prognosis is defined after 6 months from the damage and what determines it most is the presence or absence of deep pain.

MATERIALS AND METHOD

In our study we took into consideration 4 cases, of which 3 dogs and 1 cat, all visited and treated at the Clinic of Veterinary Physiotherapy Livorno (Italy). The course of the clinical condition was observed from the start of physiotherapy until the time of discharge.

The patients were followed from the first visit, collecting the anamnesis, assessing their general and particular condition, performing the complete neurological examination, examining the existing documentation and diagnostic tests.

For all patients, the following were taken into consideration: signaling, diagnosed pathology, symptoms at the beginning and end of the protocol, time elapsed between diagnosis and the actual start of the physiotherapy protocol (in days). Each subject was assigned an outcome group.

This value refers to the recovery of the patient's ability to walk correctly at the end of the rehabilitation process. Depending on the result there is a different placement for each group: if the patient has fully recovered at the end of the treatment the outcome is positive, if the degree of severity of the pathology has remained unchanged the outcome is negative. Below is the protocol applied to each patient, described in the different phases, according to the clinical condition of the subject. The application times and the manual and instrumental methods used are also reported.

MLS® Laser Therapy's efficacy in regenerating nervous tissue and managing neuropathic pain has been demonstrated in previous studies (4, 5). In this study, it has been applied with the aim to promote repair mechanisms and decrease neuropathic pain symptoms. In the cases described in this clinical study, we applied the IVDD modality along the physiological course of the nerve affected by the pathological process, depending on the lesion that the patient presented, with the aim of regenerating the injured nervous tissue and improving the restoration of the normal conduction function of the stimulus. MLS - Laser treatment was performed with a Multiwave Locked System laser (Mphi VET, ASA S.r.l., Vicenza, Italy). MLS laser is a class IV, NIR laser with two synchronized sources (laser diodes).

PROTOCOL APPLIED	
FIRST STAGE If the patient is non-ambulatory, physiotherapy for the first week is daily.	Daily therapy, from one to two weeks, to avoid neurogenic atrophy and fibrosis. Daily EMS on the muscles involved and adequate exercises, in relation to the subject, the use of the involved limb is encouraged MLS® Laser Therapy "intervertebral disc disease" (IVDD) following the course of the nerve Diathermy in athermic mode following the course of the nerve.
SECOND PHASE As soon as the support of the paw is obtained, three sessions a week, in which the instrumental techniques of the first phase are continued and the following are added:	Massages, to relax contractures and stimulate muscle function. Walking exercises with linear obstacles Proprioceptive exercises.
THIRD PHASE As the paw support frequency increases by the subject, the exercises are intensified in terms of difficulty and duration. Therapy three times a week.	In this phase, UWT exercise is added for muscle strengthening and mentally facilitating the subject to use the limb more and more.
FINAL STAGE Upon reaching the autonomous use of the paw, maintenance is continued through two sessions per week, scaling to one, until discharge.	

The two modules have different wavelengths, peak power and emission mode. The first one is a pulsed laser diode, emitting at 905 nm, with 25 W peak optical power; each pulse is composed of a pulse train (100 ns single pulse width, 90 kHz maximum frequency). The frequency of the pulse trains may be varied in the range 1–2000 Hz. The second laser diode (808 nm) may operate in continuous (power 1 W) or frequenced (repetition rate 1–2000 Hz) mode, 500 mW mean optical power output, duty ratio 50% independently of the repetition rate.

The two laser beams work simultaneously, synchronously and the propagation axes are coincident. The treatment parameters were the following: 18Hz, 100% intensity, 4,01J/cm^2.

RESULTS

As explained in the section "Material and Methods", patients were divided by outcome group based on the results obtained in the recovery of the use of the limb affected by the disease process: if at the end of the physiotherapy course they had completely recovered, the outcome was positive; if there had

Signaling	Diagnosed pathology	Symptoms at the beginning	Symptoms at the end of the protocol	Time elapsed between diagnosis and the actual start of the physiotherapy protocol (days)	Outcome group
Dog, Jagdterrier, whole male, 5 months, 7 Kg	Impact trauma, right side and consequent brachial plexus injury to the left and ligament instability of the medial compartment of the shoulder. Injury of the cranial plexus	Monoparesis left front limb, IV degree lameness, occasionally slight hint of load. Postural reactions of the left anterior limb absent, absent spinal reflexes on the left anterior limb, very slow / absent deep pain in the area of competence of the ulnar nerve	Recovery of autonomous movement of the left front limb	3	Positive
Dog, Mixed breed, whole male, 4 months, 6 Kg	Impact trauma, total avulsion of the left brachial plexus	Limb held with shoulder, elbow and wrist flexed and impossible support, severe state of supraspinatus and infraspinatus atrophy, neither superficial nor deep sensitivity distal to the elbow. Very small extensor ROM for all joints	Surgical resolution through the amputation of the paw	30	Negative
Dog, Mixed Breed, whole female, 5 years, 15 Kg	Impingement trauma, cranial brachial plexus avulsion	Monoparesis right forelimb and presence of muscular atrophy, absent postural reactions right forelimb, absent spinal reflexes right forelimb, absence of deep sensitivity, presence of multiple licking injuries and self-trauma right leg	There is still a fourth degree lameness on the front	60	Negative
Cat, Ragdoll, whole male, 2 months, 800 gr	Cranial injury of the left brachial plexus	Monoparesis left front limb, every now and then slight hint of load. Postural reactions absent left front limb, absent spinal reflexes left front limb, deep pain present	Recovery of autonomous movement and loading of the left limb	7	Positive

been no improvements, negative outcome. As shown in tab. 2, the results obtained were the following:

- 2 patients in the positive outcome group
- 2 patients in the negative outcome group.

In the positive group the subjects were a dog and a cat, in the negative group 2 dogs.

Subsequent evaluations were aimed to define which parameters had the greatest influence on the results obtained. We calculated averages in the two outcome groups by species, sex, age and the days elapsed from diagnosis to the start of the physiotherapy protocol in the different patients using an Excel sheet.

No particular links were highlighted regarding variables such as species, sex, age or weight.
As for the time interval from diagnosis to the start of physiotherapy, the average time in the positive group was 5 days. The average in the one failing was 45 days.

DISCUSSION

The 4 subjects affected by avulsion of the brachial plexus and treated at the Livorno Veterinary Physiotherapy clinic, underwent a specific physiotherapy protocol, based on exercise, laser therapy and diathermy. They were subsequently divided into outcome groups according to the result obtained.
In the event that they had recovered the autonomous movement, they were assigned to the positive outcome group; in the event that this recovery was not obtained, to that of a negative outcome.

The results obtained were 50% successful. Subsequently, further correlations were investigated. Data processing did not show any significant link between the treatment success and variables such as species, sex, age or weight. On the other hand, the time interval from diagnosis to the start of physiotherapy has proved to be important. In fact, the best results were obtained in those subjects who started the rehabilitation process early.

The average time in the positive group was 5 days, that in the negative outcome was 45 days.

Consequently, from the data obtained, it can be said that a prompt start of a physiotherapy action plan is the basis for a faster recovery of a normal movement in autonomy in the limb which was involved in avulsion of the brachial plexus.

CONCLUSION

The clinical trial aimed to evaluate the success in recovery of autonomous movement in 4 subjects affected by avulsion of the brachial plexus using a specific physiotherapy protocol consisting in exercise, laser therapy and diathermy. The results showed that the therapeutic strategy applied was effective in the 50% of the patients.

Therefore two groups were defined, depending on the result obtained, with or without recovery of the autonomous movement at the end of the rehabilitation protocol.

A further analysis of the data revealed that the treatment strategy applied was highly effective (100% success) when started promptly after the traumatic event and diagnosis of brachial plexus avulsion.

Therefore, the most important variable was the time interval from diagnosis to the start of the physiotherapy protocol. In fact, the Group with a positive outcome was the one with an average of 5 days elapsed, contrary to the one with a negative outcome, with 45 days delay in starting therapy. Consequently, from the data obtained, it can be said that a prompt start of a physiotherapy action plan, based on the protocol listed above, is the basis for a faster recovery of a normal movement in autonomy in the limb which was involved in avulsion of the brachial plexus.

ABBREVIATIONS

MNS = Upper Motor Neuron
MRI = Magnetic Resonance
CT = Computed Tomography
UWTD = Under Water Treadmill
MLS® = Multiwave Locked System
EMS = Electrical Muscle Stimulation
IVDD = Intervertebral Disc Disease

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Guide for Authors

The aim of "Energy for Health" is to spread the results of research on the application of laser and magnetic field in biology and medicine. The journal will publish studies which involve basic research and clinical trials: laser-tissue interaction, effects of laser and electromagnetic field on cells. Attention will be focused on studies devoted to explain the molecular and cellular mechanisms at the basis of the effects produced by laser and magnetotherapy.

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Articles are full-length papers presenting complete descriptions of original research, which have not been published and are not being considered for publication elsewhere.
Letters to the editor will be accepted and published if considered pertinent to the aim of the journal by the editorial board.
Reviews are topical overviews on emerging areas of research. They summarize key problems, concepts, experimental approaches, and research opportunities that characterize a subject area. Reviews should not include previously unpublished research results. The Editors generally invite them; authors who wish to submit a review should first consult with the Editors.
Case Reports will be considered if they present data with relevant clinical significance. Case Reports will be accepted if formatted as a research letter with 2 figures maximum, maximum length is up to 1000 words with up to 6 references and 2 tables or figures. There should be no Abstract and no headings.

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To keep the review time as short as possible, the authors are requested to submit manuscripts (both text and art) in electronic form to the executive editor of "Energy for Health", Dr. Monica Monici, using the following e-mail address: monica.monici@asalaser.com. Manuscripts submitted via any other method will be returned. The manuscript must be accompanied by a cover letter outlining the significance of the paper. Authors are requested to read carefully the instructions (also available at the web site www.asalaser.com) and to follow them for the preparation of their manuscript.

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Each paper must be preceded by an abstract (page 2) that summarizes in no more than 250 words a brief introduction, the aim of the study, materials and methods; main results and conclusions. It shouldn't contain any reference.

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After the abstract, in the same page, a list of 4-6 keywords should be supplied for indexing purposes.

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The introduction should describe the state of the art, give a short review of pertinent literature, state the purpose of the investigation. It should be as concise as possible, without subheadings.

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The "materials and methods" section should follow the introduction and should provide enough information to enable the experiments to be reproduced.

Patients (clinical studies): typology of patients (age, sex....), criteria for enrolment in the study, etc.
Experimental model: cellular, animal, etc.
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CONCLUSIONS
They should be concise and effective, with reference to possible involvements in the future.

ACKNOWLEDGEMENTS
Concise acknowledgements may be addressed to persons, public and private organizations, companies.

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1. Boyle WJ, Simonet WS, Lacey DL. Osteoclast differentiation and activation. Nature, 2003, 423: 337-342.

Reference to a book:
2. Michaeli W. Extrusion Dies. Hanser Publishers, Munich, Vienna, New York, 1984.

Reference to a chapter in an edited book:
3. Gmünder FK, Cogoli A. Effect of space flight on lymphocyte function and immunity. In: Fregly MJ, Blatteis CM, eds. Handbook of Physiology. Oxford:University Press, 1996, vol. 2, pp 799-813.

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