scientific report

HILT THERAPY

scientific report

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HILT – High Intensity Laser Therapy

THE UNIQUE PHYSICAL THERAPY FOR THE TREATMENT OF DJD AND OSTEOARTHRITIS.
Conventional Lasertherapy has been present in Europe since more than 25 years. More than 2000 scientific publications testify its effectiveness and the validity of this approach. It has been demonstrate moreover that it is not toxic and it has no side effects. For all these reasons it is currently used as a monotherapy or as a complementary therapy.

Up to now, conventional Lasertherapy is applied through devices featuring low or medium power, with interesting results.
Yet it does not allow to treat deep seated pathologies, since it does not permit to deliver the necessary high doses of energy to deep layers without inducing thermal damage to tissues.
For this reason traditional Lasertherapy can be applied with success only on superficial pathologies. Moreover, treatment times are moderately long.

Today, thanks to the revolutionary patented HILT Therapy, it is possible to treat also deeper disorders, since HILT features the power and the energy which are necessary to treat all the deep seated inflammatory conditions, and not only the superficial disorders. Moreover HILT is not toxic and can be performed without damaging the tissues surrounding the pathology.

HILT therefore is the sole therapeutic method which allows to treat safely all the inflammatory states, also if located in depth, inducing - since the

very first application – a strong reduction or of pain, together with the recovery of the mobility. This beneficial effect can last from 4 up to 72 hours after the first application. After some sessions the complete disappearance of pain and the complete mobility recovery can be achieved.

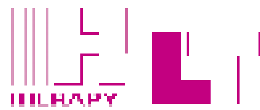
HILT is revolutionizing the therapeutic approach of orthopedic MD, physiotherapists, chiropractors, sport medicine experts etc, since its main indications are:

- DJD (Degenerative Joint Disorders) and Osteoarthritis
- Chondropathies
- Deep Musculoskeletal Disorders

PRINCIPLE OF ACTION

HILT bases its effectiveness on a particular and characteristic high peak power Laser pulse, featuring peculiar frequencies and pulse width. This Laser emission was carefully and clinically tested and found effective for all the above mentioned pathologies. Thanks to its features it is able to deliver in depth the correct effective dose of energy, without being toxic on the area of incidence and for the deep tissues it is able to reach.

Thanks to the high peak power of the pulses it exploits, HILT is able to produce also a very strong photomechanical effect: real pressure waves which propagate inside the tissues and act directly on the lymph draining pump, performing their action on the inflammatory process, even if chronic, featuring the capability of stimulating collagen and ialine cartilage regeneration. Thanks to the photomechanical effect HILT is able to produce a fast resorption of the liquids leaked because of trauma or inflammation.



The verticalization of energy

This way of energy delivery is a true “verticalization” of energy: an high amount of energy is delivered in a very short time to a great volume of suffering tissue. The traditional way of energy delivery which requires long time of emission in order to transfer the same amount of total energy, can be regarded instead as “horizontal”.
The vertical way of delivering energy is completely safe when compared to the old horizontal one, which heats up the tissues and runs the risk of damaging it. Moreover it is more effective, treating greater volumes of tissues and at same time.

THE SCIENTIFIC RESEARCH
HILT is the result of a long path of Scientific Research, co-ordinated by the efforts of a prestigious teamwork of scientists. The main biomedical and clinical results which allowed to validate HILT as a new therapeutic technique will be presented in the following pages of this report.

Cytoproliferative activity of the HILT:

in vitro investigation

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INTRODUCTION

For some time now the use of pulsed Nd:YAG Laser has been spreading in the therapy of pain with excellent results [3,4,5]. Studies exist which describe the anti-inflammatory [12], anti-oedemigenic [1] and antalgic [5,9] effects of Nd:YAG Laser, thus justifying its use in the therapy of pain.

With the exception of the study by Repice et al. [6], no bibliographical references exist indicating the cytoproliferative effect of Nd:YAG Laser in order to justify its use in reparative therapy.

On the contrary, several authors [2,8] report the cytoinhibiting effect of Nd:YAG Laser. More specifically, Sroka (1999) [8] describes having obtained a mitotic increase with Laser at 410, 635 and 805 nm while he excludes this with the Nd:YAG Laser.
In our study we have assessed the stimulating capacity of the cytoproliferation of the Nd:YAG Laser in vitro.

We used two different cell lines for investigating the cellular proliferative response to the variation in the dosimetry and for verifying the specificity of this response of a mitotic increase with the same parameters but by varying the cell line. With the use of a molecule inhibiting the tyrosine-kinasic metabolic pathway (isoflavone genistein) the metabolic interactions of the Laser radiation with one of the main metabolic pathways assigned to the cellular proliferation were assessed.

MATERIALS AND METHODS

Cell lines, culture mediums and growth conditions

We used two cell lines in this study: HCT-8 tumoural cells (human ileo-cecal adenocarcinoma) and VERO cells (derivates of renal cells of the African green monkey of the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia, Brescia, Italy).

As a culture medium for the HCT-8 line we used RPMI 1640 (Gibco – BRL, Grand Island, NY) containing 10% of bovine foetal serum (SFB,Eurobio), 1% of sodium piruvate 1mM/lt of, glutamine 2mM (Gibco – BRL), and 5% of a mixture of Penicillin-Streptomycin-Fungizone.

As a culture medium for the VERO we used Eagle's MEM containing 10% of SFB, 1% of sodium piruvate, glutamine and 5% of the antibiotic-antimicotic mixture.

Both the cell lines were cultivated in unventilated 75 mm^2 flasks until confluence in thermostat at 37°C. After trypsinisation of the monostratum, the cells of both lines were dispensed into the wells of a microtitre slide for ELISA. The quantity of cells per well was determined in such a way as to obtain the confluence within 24 hours in incubation conditions at a temperature of 37°C and an atmosphere containing CO_2(5%).

In order to avoid the diffusion of the Laser beam into the adjacent wells the treatment of each well containing the inoculum was surrounded by eight wells containing trypan blue at 0.4%[11].

Source of irradiation and irradiation conditions

As a Laser source we used a pulsed Nd:YAG Laser device (pw: pulsed wave), 1064 nm, average power 6 Watts (El.En. S.p.A., Calenzano, FI, Italy), with a 0,19 cm^2 spot. The handpiece was fitted with a spacer in order to guarantee a lens-well distance allowing the spot to assume a diameter capable of ensuring the exact coverage of the irradiated well.

To protect the cells from radiation scattering each well sown was surrounded by eight wells containing a trypan blue (0,4%) solution (Grossman, 1998)[11].

The wells were irradiated 6 h after being sown, by replacing the culture medium with sterile PBS sterile.

We performed the assessments by maintaining the energetic contents of each pulse constant: 150 mJ, while we varied the repetition frequency (5 – 40 Hz) of the pulses in one second and the irradiation time (4 – 20 sec) of the well.
After the treatment the new culture medium replaced the PBS in the wells and the slides were then further incubated for another 10 hours, for up to a total of 16 hours of incubation after the sowing.
The control cells were instead irradiated with an ineffective Laser called a “sham Laser”.
Each test was repeated five times.

Proliferation parameters

SPECTROPHOTOMETRY

At the sixteenth hour, the culture medium was replaced with 200µl of new medium added to 50µl of solution containing 3mg/ml of MTT (Sigma, Italy) in PBS. After an additional 4 hours of incubation under the same conditions, the solution contained in the wells was replaced with 200µl of dimethyl sulphoxide (DMSO, Sigma) to which 25µl of a solution of 0.1 M of glicine and 0.1 M of NaCl with a pH of 10.5 were added. The slide was then immediately read with a spectrophotometer operating at a wavelength of 450nm.
Each slide was then irradiated at specific values after which all the values of the spectrophotometric readings were expressed in O.D. (Optical Density) which indirectly indicates the density of the vital cells of the monostratum.
They were then compared with the average values of the non-radiated control cells or irradiated with the sham Laser.

IMMUNOHISTOCHEMISTRY (IHC)

“Chamberslide” (Bibby, Sterilin) slides were used for the immunohistochemistry tests, sowing and later irradiating each well in the same manner as described for the ELISA slides. The groups of treated and control cells were prepared in the same way as described for the spectrophotometric examination for both the VERO and the HCT-8 line. Once the

treatment was over, the culture medium was removed from the wells and the monostrata fixed with methanol for 10′, followed by three rapid lavages in PBS. The monostrata were then incubated for one night with the following primary monoclonal antibodies: specific antibody for antigen Ki67, clone MIB-1, (DAKO) diluted at 1:50 in PBS+BSA, anti-PCNA antibody (Novocastra) diluted at 1:50, anti-Cyclin D1 antibody (Santa Cruz) 1:100, anti-ILGF-1 antibody (Santa Cruz) at 1:200. After three 10′ washings in PBS, the monostrata were incubated for 15′ with a secondary antibody (horse-anti mouse biotinylate, 1:250 in PBS+BSA), then washed again three times in PBS and incubated for another 45′ with the Avidin-Biotin (ABC, Vector).
Finally the immunohistochemical reaction was visualised via incubation with the chromogen substrata, represented by diaminobenzidine (brown dye) for the PCNA and the ILGF-1, by Nova Red (red dye) for the Cyclin D1 and Vector Red (crimson dye) for the Ki67. In order to assess the expression level of the single antigens we proceeded with the reading of the preparations with a 440x magnifying optical microscope, directly counting the number of positive cells per field, in ten fields selected randomly. We then calculated the average of the values obtained and compared the averages of the irradiated monostrata with those of the control monostrata.

Treatment of the monostrata with genistein
In order to carry out an assessment of the tyrosine-kinasic metabolic pathway we used monostrata cultivated on microtitre slides. These were treated with a isoflavone genistein solution (Sigma, Italy) capable of inhibiting this metabolic pathway.

The monostrata were then treated with decreasing doses of genistein, with the addition to the culture medium of a 400 mMol solution from a concentration of 100ml which was cytotoxic, up to concentration of 50ml, which was instead cytostatic.
The dose with the cytostatic effect was identified by means of the use of the spectrophotometric technique described above, and via the direct

assessment of the mitotic index of the monostrata treated with the genistein and the controls. More specifically, these cells were treated first with Colcimit® in order to evidence the chromatids, lysed in hyperosmolar buffer, fixed in methanol, dyed with Giemsa, after which the count was performed of the number of metaphasic nuclei out of one thousand nuclei counted.
Once the dose inhibiting the cell cycle was identified, the monostrata were irradiated once again with the Nd:YAG Laser with the values identified during the first part of the study, that had demonstrated their ability to increase the mitotic index.

Statistical analysis
The average of the samples and the standard deviation were calculated for each experimental conditions, repeated five times. The results of the repeated experiments carried out for each cell line were added by percentage and compared with their controls. The onetail Student t-test was used for evaluating the differences between the controls and the treated group.

RESULTS
The irradiation of the monostrata with the Nd:YAG Laser at specific frequency values, intensity and exposure time induces cell proliferation.
For each test performed for both the HCT8 and the VERO we then compared the O.D. values deriving from the spectrophotometric reading of the irradiated wells with the O.D. values of the control wells.
We compared the average of the differences (each calculated on the five tests performed) between the two groups under investigation at the varying of the exposure time (sec.), frequency (Hz) and therefore, automatically the average power (Watts).
Out of the 120 tests conducted, 60 per cell line (divided into 12 “groups” of parameters with five tests per group), it emerged, as in figure 1, that the comparison between the differences between the control and treated groups was statistically significant (indicated in the graph with the posi-

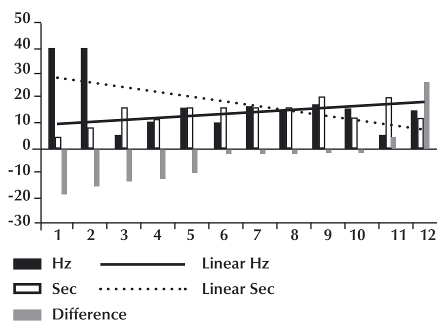

Fig. 1 - *Cytoproliferative parameters. Shape of each pulse is constant, only frequency and time are varied.*

Frequency (Hz)	*Time (s)*	*O.D. Difference (Treated – Non treated)*
5	12	-11.95
10	16	-1.72
5	16	-13.08
15	16	-1.13
16	16	-9.60
16	12	-0.67
40	8	-4.00
40	4	+22.45
5	20	+3.45
17	16	-1.26
17	20	-1.00

Fig. 2 - *Assessment of cytoproliferation after HILT treatment (VERO cells).*

tive ordinate value) with medium-low frequencies and exposure times. In this respect it is to be noted that in this study we maintain the energetic content of each pulse constant (150 mJ) and varied only the frequency and irradiation duration. More specifically, for the HCT8, the window of optimal values turned out to be the one corresponding to a quantity of energy equal to 2.7 Joule, and average power of 2.25 Watts, a fluence of 14.2 J/cm^2, and intensity of 11.8 W/cm^2, a repetition frequency of the pulses in one second of 15 Hz for an exposure time equal to 12 seconds, while for the VERO the greatest proliferation was obtained with 2.4 Joules, 6 Watts of average power, 12.6 J/cm^2, 31.5 W/cm^2, and 40 Hz for 4 seconds (Figure 2). From this data it emerges that the value window identified for the HCT8 cells was ineffective for the VERO cells, even creating a cytostatic effect.
The "windows" with a cytostimulating action are characterised by high levels of nuclear expression of the antigens PCNA and Ki67, as well as by an elevated mitotic index. From the direct count of the nuclei expressing the antigens Ki67 and PCNA, statistically significant differences have come to light between the treated and control monostrata.

In fact, in the monostrata subjected to irradiation with cytostimulating parameters (cyto-proliferative windows) mean expression values of the above-mentioned antigens were observed which were on an average double those shown in the control monostrata. The results appear to be in constant correlation with the mitotic index calculated on the two cell populations and assessed on average as double in the treated monostrata compared to the controls.

Cytostatic effect of the genistein and restoring the cell cycle after irradiation of the monostratum.
A cytotoxic effect was observed with a dose of 100 µl of genistein added to the medium culture, while 50 µl gave rise to an inhibiting effect of the cell cycle. 25 µl and 12.5 µl doses produced intermediate effects, not totally inhibiting of the cell multiplication.
With 50 µl doses in fact, it was possible to observe the zeroing of the

mitotic index as well as the absence of expression by the cells treated with antigens like the Ki67 and PCNA, Cyclin D1 and the growth factor ILGF-1. These results have only been obtained on the HCT8 cell line, seeing that for the VERO cell line it was not possible to identify a concentration of genistein which, when added to the culture medium, was capable of inducing a cytostatic effect free of partial or total damage to the monostratum (cytotoxic). The Laser irradiation of the culture with the cytoproliferative parameters after the cytoinhibiting effect by means of the isoflavone genistein, resulted in being capable of reactivating the cellular cycle despite the block operated by the isoflavone on the tyrosinkinasis.
This metabolic pick-up is quantifiable by means of the cell count in metaphase (newly assessable mitotic index), and also via cellular neo-expression of the Cyclin D1 and the ILGF1.

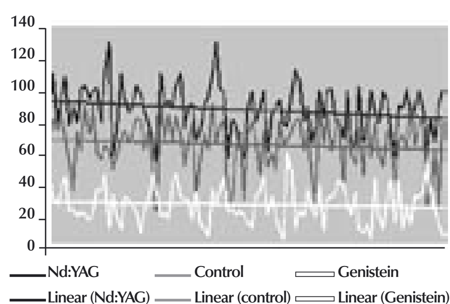

Fig. 3 *- The mitotic index of the cells treated with genistein is clearly lower than that of the cells treated with HILT.*

Figure 3 contains the graph describing the distribution of the mean values, evidenced by the linear for each group. From the graph it can be seen how the level of the mitotic index of the cells treated with genistein is clearly lower than that of the cells treated with the Nd:YAG.

DISCUSSION

The results obtained with the spectrophotometer (indirect assessment) and with the immunohistochemistry (direct assessment) indicate the capacity of the Nd:YAG Laser to induce the proliferation of the HCT-8 and the VERO at specific frequency values, exposure times, pulse shape.

The different reaction of the monostrata even with very slight changes in the irradiation parameters indicate how there is an elevated specificity between dosimeter and effect; in fact we have observed how the administration of similar energy quantities (Joule), obtained by varying the frequency (Hz) and the exposure time (sec) are able to supply biological effects which at times are diametrically opposite.
This indicates that more important than the quantity of energy transfered

to the system (Joules), is the way in which this energy is supplied: frequency and exposure time.
The fact that there is a variation in the parameters that are cytostimulating with the varying of the cell line used, indicates a considerable specificity of the Laser action, depending strictly not only on the quantity of energy supplied but also on the type of biological substratum on which it is used.
In fact by applying the cytostimulating dosimetric parameters to different cellular lines as indicated by other Authors [6] there is no increase in the mitotic index. Repice et al. [6] have described the biostimulating effect of the Nd:YAG Laser on human neuroblastoma cells using parameters that are very different from those used in this study. Other Authors [2,8] have even described a constant inhibiting effect of the Nd:YAG Laser on the cellular proliferation. More specifically, Stroka [8] reports of no cytoproliferative effect at all in the interval between 0 – 10 J/cm_2 which results in being very similar to our study (7.69 J/cm^2). For this purpose, and reiterating what has been reported with regard to the specificity of the parameters and the extreme sensitivity of the cells to the Nd:YAG Laser we can state that in the light of our results, it is not sufficient to indicate the fluence for establishing the parameters of effectiveness of lack of effectiveness since it is necessary to identify an effectiveness window of energy supply values for every cellular substratum, and these parameters must refer to the specificity of the cellular line used.
In any case, on having confirmed the biostimulating effect of the Nd: YAG, we believe that this is capable of justifying its use in repair therapy as well as in pain therapy [3,4,5,9]. Despite being only preliminary, the results obtained with the double genistein-Laser radiation treatment of the HCT8 cell line indicate the possibility of unblocking the cellular cycle interrupted with the genistein by irradiating the cells.
In fact, even though the blocking of the cellular cycle by the genistein during the G0 phase (indicated by the inhibition of the expression of the cycle markers Cyclin D1 -expressed by the cells that progress from the G1 phase to the S phase- Ki67 and PCNA -both expressed in the S, G2 and M phases- and by the zeroing of the mitotic index via selective

inhibition of the tirosine-kinasic metabolic pathway) the exposition to opportune doses of Nd:YAG Laser radiation has allowed for restoring the cellular cycle. This element is particularly interesting if assessed within a therapeutic context. In fact, it is known that the homeostasis of the cartilagineous turnover is guaranteed by the balance of the catabolic factors (IL 1 beta, TNF alpha, IL 6, IL 8) and anabolic factors (ILGF-1, GH, TGF beta) that act through the same family of receptors (GH–Citokine) in the metabolic pathway of the tyrosine kinase. A competitive mechanism is therefore hypothesised in the substratum, for which in cases of prolonged stress, the metabolic factors are not able to use the metabolic pathway of the tyrosine kinase and the tissue proceeds towards the degenerative phenomenon. This study therefore sheds light on the capacity of Nd:YAG Laser to promote the restoring of the cellular cycle in spite of the selective block operated on the tyrosine kinase.

CONCLUSIONS

This study also demonstrates that like other lasers, the Nd:YAG Laser possesses the biostimulating capacities even though there is an extremely high sensitivity of the in vitro cells to the variations in dosimetric parameters (mJ, sec, Hz).

The most striking element arising from this study is that in order to induce the cytoproliferative effect, the manner in which this energy is supplied (frequency and exposure time) seems more important than the dose.

Moreover, this radiation seems capable of reactivating the metabolic pathway of the tyrosine kinase on which a pharmacological block is activated; this element could explain why the degenerated tissues in which this metabolic pathway is blocked are able to recover the anabolic phase and re-equilibrate their homeostatic balance.

We believe further investigations are necessary for confirming our observations, above all in the aim of identifying the cytoproliferative parameters of other cell lines, especially the primary type.

The acquisition of this data could in fact open up the field of Nd:YAG Laser use in both reparative and pain therapy.

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High Intensity Laser Therapy in arthrosis:

experimental investigations on animal models

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INTRODUCTION

Arthrosis is a disease with a high social impact as it affects 30-35% of the population. An arthrosic patient costs the public health services approximately 4,000 euro on average a year, touching peaks of almost double this amount in the most severe cases [1].

Conventional therapy foresees the administration of anti-inflammatories, antalgics, and decontraction agents. The current trend is to use chondroprotective drugs with often encouraging results [2].

The international bibliography provides results that are often contrasting with regard to the clinical effectiveness of the Low Level Laser Therapy (LLLT) in the treatment of arthrosic and rheumatic complaints, and some even express negative opinions [7, 8, 9, 10, 11, 12, 13, 14, 15], while others are positive [16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26]. Over the last few years the High Intensity Laser Therapy (HILT) has been making its mark with excellent results in sports traumatology and pain therapy [27, 28, 29, 30], for this reason we decided to assess the possibility of also transferring this method to the cure of arthrosic ailments and therefore prepared an animal model with an arthrosic pathology in line with the indications of the various Authors [3,4, 5].

The majority of studies conducted over the last thirty years in Laser therapy have been carried out with medium and low intensity Laser devices (Low Level Laser Therapy: LLLT), with wavelengths in the infrared and near infrared (600 - 900 nm). Within this spectrum the Laser beam is partially absorbed by the natural chromophores, like melanin, which withhold part of the energy irradiated.

Our study on the other hand is based on the use of a Nd:YAG High Intensity Therapy (HILT) Laser, characterised by a wavelength (1064 nm)

Wawe-length (nm)	Average intensity used (watts)	Spot area (cm^2)	Power density (W/cm^2)
Laser Nd:YAG			
1,064	1.9	0.19	10
Laser Nd:YAG			
1,064	5.7	0.19	30
Laser Nd:YAG			
1,064	9.5	0.19	50
Laser Nd:YAG			
1,064	10	0.125	80
Laser CO_2			
10,600	5	1.5	3.3
Laser DIODE			
830	1	0.03	33

Table 1. *Types of lasers and dosimetric Parameters used.*

that allows it to penetrate and spread more easily through the tissue due to not having an endogenous chromophore. Moreover, with the pulsed wave Nd:YAG it is possible to deliver power peaks of up to 1000 Watt for times of 200μ seconds: extremely elevated peak intensity (W/cm2) in very brief times. Such a high intensity in such a short time prevents the heat accumulation by the tissues as happens with the use of Nd: YAG with constant emission (Parra [29, 30]). This all extrinsicates in a greater spreading capacity of the Laser beam through the tissues with a very low histolesive risk.

In other words, quantities of energy (Joules) and fluence (J/cm^2) are delivered in the HILT that are not dissimilar to the ones delivered with the LLLT but there is an intensity (power density: W/cm^2) of even up to 1000 times higher.

The objective of this study was to assess the safety of intensity Laser at various power intensities (10, 30, 50 and 80 W/cm^2) used on the superficial and deep structures.

The secondary objective was that of verifying the biological effects in vivo of the three different types of Laser: CO_2, Diode, Nd:YAG; and more specifically, we assessed the antalgic [32], antinflammatory [33] and cytoproliferative [34] effects of the Laser.

MATERIALS AND METHODS

Lasers used

Three types of Laser were used: CO_2 (10.600 nm), Nd:YAG pulsed wave (1.064 nm), Diode (830 nm) produced by El.En. S.p.A. (Calenzano - Florence). Table 1 shows the powers used by the three lasers assessed.

Investigation population

According to Bentley [3] the ideal animal model for the study of arthrosis should have the following characteristics:

- the presence of precocious lesions and action mechanisms similar to those described for the human pathology;
- evidence of an initial loss of the cartilagineous matrix and subsequent

Healthy	12
Control	20
Nd:YAG 10 W/cm²	12
Nd:YAG 30 W/cm²	12
Nd:YAG 50 W/cm²	12
Nd:YAG 80 W/cm²	12
DIODE	12
CO_2	12

Table 2. *Breakdown of the subjects in the investigation groups*

appearance of fissures, fibrillations and erosions;
- the cartilagineous lesions must therefore be followed by sclerosis of the subchondrial bone;
- the alterations described must be readily reproducible and identifiable in the living animal;
- the induction method of the lesions must be valid for different animal species and articular sites and free from systemic effects.

In this study we chose chickens of the heavy breed, bred with the open range system to allow ample possibility for deambulation.
This species was preferred over others as it has a bipedal gait similar to man, ample articulations capable of supported heavy loads and an elevated basal metabolism that allowed us to obtain chronic degenerative lesions in relatively brief times, a good-natured disposition making it easy to treat with Laser. Moreover, it expresses a range of cytokins and chemokins that can be compared to those of humans.
Table 2 illustrates the breakdown into groups of the population investigated.

Investigation protocol
The investigation was performed in compliance with the Helsinki Declaration and the International Standards governing research on animals.
The chronic degenerative arthrosic phenomenon was induced via double inoculation in the lower right limb of each subject with Freund's Complete Adjuvant (FCA) + formaldehyde at 10%.
The inoculations were administered at one-month intervals. Eight months after the second infiltration the Laser therapy was commenced.
Following is a list of the activities in chronological order with the specific examinations performed;
A) acquisition of subjects;
B) one month's growth;
C) 1st inoculation with FCA;
D) one month's growth;
E) 2rd inoculation with FCA;

F) growth after 8 months;
G) beginning of Laser therapy:
- T/0 => on all subjects: Rx, clinical evaluation of the lameness, weight, blood tests; bioptic analysis on 8 controls (after euthanasia with general anaesthetic).
- T/1 => beginning of Laser therapy.
- T/2 (3 weeks after T/1) => end of Laser treatment: in all 15 Laser sessions were performed spread over three weeks.
- T/3 (2 weeks after T/2) => on all the remaining subjects: Rx, clinical evaluation of the lameness weight, blood tests; bioptic analysis (after euthanasia with general anaesthetic).

Assessments carried out:
- X-rays in both lat-lateral and antero-posterior of both limbs of each subject.
- Serological analyses (ELISA) for: PCR, IL 1 beta, ILGF 1, TGF beta.
- Macroscopic examination via photographic acquisition.
- Microscopic examination: histological and immunohistochemical examination (IHC): histogical staining with hematoxilin-eosin, Herovici polychrome solution and Alcian PAS blue.
- In IHC we performed assessments for: Type II Collagen, ILGF 1, MMP1, TIMP2.
The stainings with Herovici were performed in order to highlight the presence of protocollagen (pale blue) as a demonstration of the age of the cartilage: the protocollagen precedes the formation of collagen.
The synthesis activity of the mucopolysaccharidic matrix was instead assessed via the Alcian PAS blue.
The data collected were entered onto an electronic spreadsheet and analysed statistically with the t-Test.

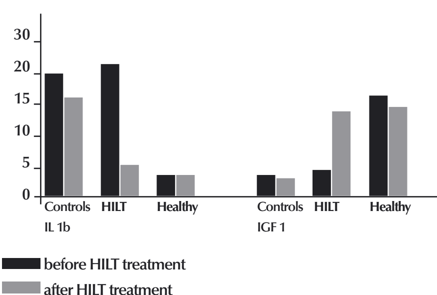

Fig. 1 *- Effect of HILT treatment on inflammatory (IL1-beta) and anabolic (IGF1) cytokines*

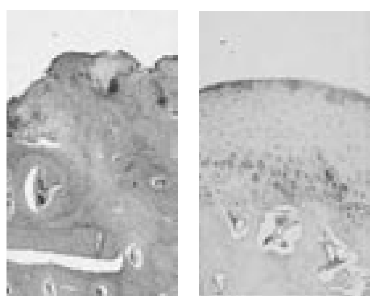

Fig. 2 ***Fig. 3***

Fig. 2 *- Control. Articular cartilage almost completely dextruded and destructured. The image is characterised by the almost total presence of bone tissue: the haversian systems are evident.*

Fig. 3 *- Nd:YAG 50 W/cm². Neoformed and physiologically structured hyaline cartilage. Confirmation that this is hyaline cartilage was obtained in IHC for the Type II collagen while the presence of protocollagen (Herovici's polychrome) testifies to the young age of the same.*

RESULTS

Anti-inflammatory effect

The graph in fig. 1 illustrates the mean of each subject treated with Laser with a comparison between the Controls and the Healthy subjects.

Neochondrogenic effect

The neochondrogenic effect was documented histologically and immunohistochemically (IHC). Figures 2 and 3 show the histological images referring respectively to a Control (fig. 2) and a subject treated with Nd:YAG at 50 W/cm² (fig. 3).

Fig. 2 shows the almost completely dextruded cartilage with partial covering of the subchondral bone tissue where in fact the haversian systems can be observed. In fig. 3 instead, there is neoformed cartilage structured according to the physiological architecture on the subchondral bone tissue; basal globiform isogen groups can be recognised which on moving towards the surface tend to arrange themselves parallel to the articular surfaces.

DISCUSSION

From an analysis of the graph in fig. 1 it is apparent that all the types of Laser used have carried out an anti-inflammatory effect (see the curve of the IL 1beta).

As far as the historegenerative effect on the articular cartilage is concerned however, we observed a different effect between the different types of Laser. The CO_2 Laser offered less biostimulation.

The diode Laser offered greater stimulation compared to the CO_2 but failed to induce the synthesis of very active isogen groups which were however very dishomogeneous in shape and distribution. Moreover, the immunohistochemical examination of the Type II collagen indicated that it was fibrocartilage.

It is a completely different situation with the Nd:YAG Laser which proved to be far the most effective in the neochondrogenesis activity.

Having tried various power intensities we were able to observe a linear

Morphology	Type II Collagen	ILGF 1	MMP1	TIMP1
Healthy				
+++	+++	+++	-	+++
Controls				
-	-	-	+++	-
Nd: YAG 10 W/cm²				
+	+	+	++	+
Nd: YAG 30 W/cm²				
++	++	++	+	++
Nd: YAG 50 W/cm²				
+++	+++	+++	-	+++
Nd: YAG 80 W/cm²				
+	+	+	++	+
CO_2				
-	-	-	++	-
DIODE				
+	+	+	++	+

Table 3. *Histological evaluations and IHC per group; classification with 4 degrees of merit: starting from the lowest we have:* - , +, ++, +++

trend between the therapeutic response and the dose supplied. In fact at 10 W/cm2 we observed the presence of the activation threshold with the proliferation of the basal isogen groups, at 30 W/cm^2 homogeneity was observed in both shape and spatial distribution of the isogen groups, at 50 W/cm^2 we identified the most effective dose for stimulating the physiologically structured hyaline cartilage, while at 80 W/cm^2 we observed tissular regression above all on the surface, and the lack of chondrocyte action of the Type II collagen (table 3).

The curve of the ILGF-1, MMP1 and TIMP2 were particularly interesting in immunohistochemistry. As far as the IGF-1 is concerned, an expression was observed in the CO_2 which was comparable to that of the CTR group. The degree of expression of the growth factor with the Diode Laser was not dissimilar to that of the CO_2. With regard to the degree of expression in the subjects treated with the Nd:YAG Laser, this faithfully reflects the expression of the Type II collagen with a better expression than subjects treated with 50 W/cm^2.

The trend of the MMP1 and TIMP2 in immunohistochemistry was also very interesting. In this case a sharp difference was observed between the MMP1 and TIMP2 in the CTR, which was less marked with the CO_2, diode, and Nd:YAG at 30 W/cm^2, whereas it was highly significant with the Nd:YAG at 50 W/cm^2. Obviously this different expression of the MMP1 and the TIMP2 has opposed trend between the CTR and the Nd: YAG group at 50 W/cm^2. In fact, in the CTR we obtained a high value of MMP1 and a low value of TIMP2, while in the Nd:YAG at 50 W/cm^2 these were exactly the opposite.

CONCLUSION

From this study it has emerged, in primis, that the High Intensity Laser Therapy, when administered at suitable doses, is safe in the treatment of articular pathologies and does not induce lesions to the surface and deep structures.

This study indicates that the Laser is capable of antagonising the experimentally induced athrosic phenomenon to stimulate the neochon-

drogenic activity with the formation of hyaline cartilage and to induce sinovial hyperplasia.
These effects are closely linked to the dose supplied. More specifically, we varied the intensity (power density: W/cm^2) and maintained constant energy (Joules) and fluence (energy density: J/cm^2).
It was therefore observed that the low intensity only has an anti-inflammatory effect while the high intensities have a neochondrogenic and sinovial hyperplastic effect as well as the anti-inflammatory effect.
As this was a pilot study we believe that further investigation and confirmation are indispensable. We are also of the opinion that it would be important to perform verifications on spontaneous arthrosic pathologies in animals.

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High Intensity Laser Therapy in the treatment of gonarthrosis:

the first clinical cases and the protocol for a multicentric, randomised, double-blind study

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ARTHROSIS: STATE OF THE ART

Cartilage possesses scarce reparative capacities and until several years ago spontaneous or therapeutic repair of an articular lesion was not considered possible. At the present time the most common cartilaginous pathology, Arthrosis (osteoarthritis) is the focus of great interest on a worldwide level and has become the "new frontier" not only for orthopaedics but also for rheumatology and rehabilitation, to which a great deal of energy and resources are dedicated.

Arthrosis is certainly the disease with the greatest increase in the number of cases in the western world in consideration of the general aging of the population.

The social and economic role of arthrosis is therefore potentially very high. Numerous drugs have been proposed for the therapy of arthrosis including:

- the new FANS (selective inhibitors of the COX 2),
- basic drugs: DMOADs (Disease Modifying Osteoarthritis Drugs)

better known as chondroprotectors, theoretically capable of intervening in both the destructive and reparative process of the disease, which include galactosamineglucuronoglican sulphate, diacereine, jaluronic acid.

The real effectiveness of the DMOADs still has to be demonstrated and the clinical impression is that these molecules represent the forerunners of a new generation of drugs.

Orthopaedics have developed a series of reparative surgical interventions of great interest aimed principally at knee-cartilage reconstruction.

The techniques are divided into two groups: bone marrow stimulation

techniques and tissue transplant techniques. Worth noting among the marrow stimulation techniques are chondroabrasions, perforations and microfractures. These methods tend to stimulate the subchondrial bone and fill the cartilaginous lesions with fibrin coagula, rich in totipotent stem cells. These techniques give rise to the formation of fibrocartilaginous tissue (Type I collagen) with scarce mechanical capacities.
These interventions are currently reserved for lesions of less than 2 cm^2, and are generally performed in arthroscopy, in one single diagnostic-surgical session.
Far more interesting are the tissular transplant techniques (homologous transplants, multiple or mosaicoplastic autologous transplants, autologous transplants of periostal flaps, autologous chondrocyte transplants), which aim at reconstructing the physiological hyaline cartilage (Type II collagen), with good mechanical capacities.
Amongst these techniques the implanting of autologous chondrocytes (ACI) has been particularly successful. This method consists essentially of arthroscopic extraction of the chondrocytary cells from areas not subjected to stress and transplanting of the same in the athrosic lesions.
This is carried out in 4 stages:
1) arthroscopic extraction of the cells;
2) creating of cell cultures in highly specialised laboratories
3) mounting of biomaterials deriving from the collagen
4) transplanting of the neo-tissue in the lesion.
These methods have opened futuristic scenarios which are already partially in progress. Mesenchymal cells deriving from the bone marrow and futuristic three-dimensional biomaterial deriving from hyaluronic acid (non-material materials) are already being tested in laboratories and animal models. These new surgical frontiers must not distract us however from the globality of the arthrosis problem.

Contra-indications to transplants
The presence of significant axial deviations (greater than normal varus or valgus knee greater than the norm of 5°) is considered as a mechanical imbalance capable of compromising the positive results of the trans-

AUTHOR	AV.AGE/ PATIENT	NUMBER OF PATIENTS
Berruto	28	13
Gobbi	40	50
Cherubino	34.5	18
De Santis	33	24
Gualtieri	36	40
Faccini	33	16
Lo Bianco	34.5	36
Radosavjei	37	10

***Table 1.** Average age of clinical cases subjected to chondrocyte implant. From 1st G.I.R.C. conventIon Ischia 20-22 Sept.2001*

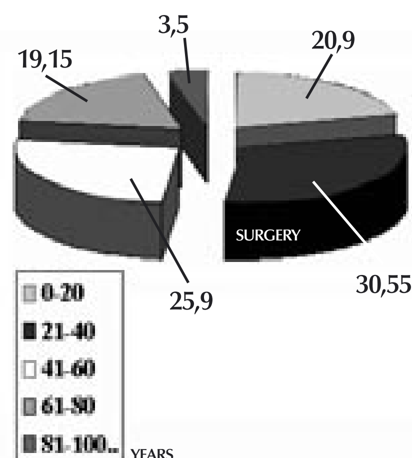

***Fig. 1 -** Distribution of arthrosis throughout the Italian population.*

plant; all deviations should be corrected in a preliminary manner. At the same time the absence of the meniscus due to previous meniscetomies is considered as a potentially unfavourable situation for transplants. The simultaneous presence of multiple cartilaginous lesions calls for a careful assessment of the suitability of resorting to chondrocytary implanting or similar techniques.
More general conditions like overweight and an advanced age are other factors considered as very important in subjecting the patient to reparative surgery of the cartilage.
We only considered the patient's age since, as Pellaci states, if all these selective criteria were to be complied with, in practice, only very few patients would be proposed for this type of surgical treatment.
In international literature it is advised against performing transplants in patients over 55.
In actual fact, the age of the patients subjected to surgery is always low: at the recent convention of the Gruppo Italiano di Studio dei Processi Riparativi del Tessuto Osteo-Cartilagineo (G.I.R.C. – Italian Study Group of Reparative Processes of Osteo-Cartilaginous Tissue at Ischia 20-22 September 2001) the mean age of transplants resulted in being 34 years, with a minimum of 15 and a maximum of 40 (see table 1).

If we consider the wide range of the population over 55 we are able to realise how a univocal answer to arthrosis cannot be found in surgery alone (see fig. 1).

High Intensity Laser Therapy (HILT)

Over the last ten years numerous studies have been carried out indicating the biostimulating action of MID lasers. In particular, lasers have been accredited with the power to accelerate the healing of skin ulcers and bedsores. The Laser devices used until now have been low intensity with a wavelength of 600-900 nm, corresponding to the near infrared. Within this spectrum the Laser beam can be absorbed by the natural chromophores like melanin for example.

The CO_2 Laser represented the introduction of high intensity Laser in the medical field. Unfortunately, due to its wavelength (10,600 nm) it is completely absorbed by the water resulting in an extremely scarce penetration of the tissues.

Its action is prevalently analgesic, acting on the sensitive cutaneous nerve endings. We have recently analysed the physical properties of high intensity Nd:YAG Laser that has a wavelength of 1064 nm.
At this frequency the Laser beam is easily diffused throughout the tissues. More specifically, the cartilagineous and bone tissues turn out to be excellent targets for this type of radiation. In the past this Laser was applied with continuous emission and given its high intensity there was a considerable increase in the heat produced with histolesive risks. This aspect obviously prevented its use. Approximately three years ago we developed a new Laser with pulsed wave emission capable of supplying high intensities without inducing heat effects and without causing cellular damage. We have tried to evaluate whether the Nd:YAG Laser had the same trophic effects in depth at the articular level that the MID lasers had already demonstrated to possess on superficial skin tissues. The results of the experimental studies performed on animal models and the in-vitro cellular studies carried out throughout 2000 and 2001, have demonstrated the possibility of stimulating the formation of hyaline cartilage by means of Laser stimulation. This fact has led us to consider the feasibility of clinical experimentation in humans.

PRELIMINARY CLINICAL STUDY

For six months we have been carrying out a preliminary study at the Servizio di Recupero e Rieducazione Funzionale (Recovery and Functional Re-education Service) of the Rizzoli Institute of Orthopaedics, in the aim of exploring the investigation methods and therapeutic parameters most suitable for performing a double blind experimentation.
10 patients have been selected (mean age 50 years, min. 41 years, max. 65 years, 5 females, 2 males) affected with primitive arthrosis.

Clinical tests

The clinical tests considered most suitable were as follows.

The W.O.M.A.C. (Western Ontario and Mc Master Universities Index), consisting of a clinical functional test specifically for osteoarthrosis (the W.O.M.A.C. is the only test among those used in an international context to have been validated for Italy). It is easy to implement and explores both the functional attitude of the arthrosic knee and the patient's daily activity.

The IKDC test is a functional test of the knee consisting of a section with the patient's subjective assessment of his/her own conditions in relation to his/her daily and/or sporting activities, and a clinical and objective assessment by the physician. It is extremely valid in the event of the patient having been subjected to arthroscopy or being a candidate for reparative knee surgery, for which he/she has not been considered in the final assessment of the pilot study.

V.A.S.*(Visual Analogic Scale)* is the traditional scale for a quantitative assessment of pain which consists of a simple test with easy acquisition and comparability.

As laboratory analyses the following classical phlogistic tests were implemented: ESR, PCR, α1glycoprotein, as well as several Interleukin and ChemiKine assays like: IL1ß, IGF 1, IL8 and RANTES, as an expression of the metabolic activity of the articular environment affected by arthrosis.

Instrumental diagnostic tests

As an initial sidetracking from the arthrosis we performed a conventional X-ray of the knee in an antero-posterior position under stress, after which we classified the lesions using the Ahlbach's guide.

The patients classified under grades II and III were then subjected to a nuclear magnetic resonance.

DEGREE	RADIOGRAPHIC ALTERATIONS
I	Slight reduction in height of the femurotibial space (<50%)
II	Obliteration of the femurotibial space (>50%)
III	Moderate bone wearing away (<7 mm.)
IV	Significant bone wearing away (>7 mm.)
V	Significant bone wearing away with articular sub-dislocation

Magnetic resonance
A last generation MR device with 1.5 T was used. Where possible we compared photographic images of the arthrosic lesions obtained with arthroscopies, with the images obtained from the various MR sequences.
From the numerous tests conducted, the most suitable weights for defining the arthrosic alterations were the sequences in T2 and the SPGR suppressed fat performed according to sagittal and coronal planes.
Subsequently, it was considered opportune to use the three-dimensional methods for volumetric acquisitions.

Ultrasonography
The most suitable optical "windows" of the patients in the preliminary study were assessed via ultrasonography in order to allow for the diffusion of the Nd:YAG Laser.
These windows resulted in being the internal and external hemi-rima of the knee bent to 90° for the anterior chondyles and the internal and external hemi-rima of the knee in the popliteus hollow at maximum extension for the posterior chondyles. In order to access the posterior face of the patella the best lateral and middle windows appeared with the knee bent to 30°.

Therapeutic protocol
As a therapeutic protocol a total of 2500 m Joule were delivered in pulsed waves with manual scansion with a last generation Nd:YAG Laser with an average intensity of 6 W. The treatment was carried out once a day

for 15 days over a period of three weeks (excluding holidays). After three months the entire therapeutic cycle was repeated. At the beginning (T0) and at the end (T1) of the first cycle, and likewise at the beginning (T2) and at the end (T3) of the 2nd cycle of treatment the algo-functional assays (W.O.M.A.C. and V.A.S). and the laboratory tests: ESR, PCR, 1αglycoprotein, IL 1ß, IL 8, h-RANTES and IGF-1 were carried out.

STATE OF PROGRESS

Seven out of the 10 patients selected completed all the clinical instrumental tests envisaged.

Clinical tests

The clinical tests VAS and WOMAC evidenced a constant improvement of both the algic and functional symptomatology.
At the end of the second Laser cycle the patients showed a reduction in pain equal to 51% (V.A.S.) and a reduction in the functional limitation (WOMAC) equal to 49%.

Lab tests

The classical phlogosis assays showed negligible variations with values always recorded within the normal range or very close to the same. Nevertheless it is worth pointing out how the trend of the ESR and PCR values, as well as the alpha 1 glycoprotein values appeared to be substantially similar. The values tended to rise after each Laser cycle and then return to the basic values again. The Nd:YAG Laser seems to have altered the quiescence of the articular environment. The scarce specificity of these classical indexes do not however allow us to understand further the metabolic alterations of the cartilaginous tissue.
The data obtained from the Lymphokin and ChemoKin assays appears far more significant. As regards the IL 1ß, which is the expression of the chondrolytic and pro-inflammatory activity at the level of the cartilaginous tissue, a constant diminishing trend from T0 to T3 has been observed. This datum is confirmed by the results obtained by the IGF-1,

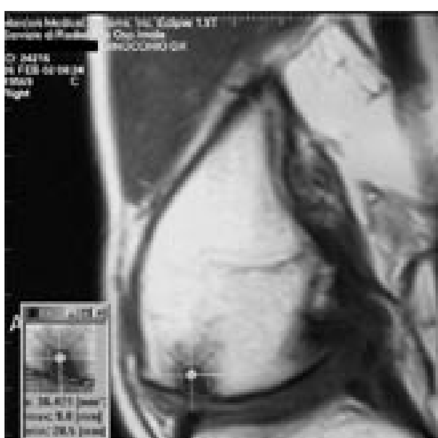

Fig. 2 - *Measurement via NMR of the area of the ulcer.*

a growth and replicative activity factor of the chondrocytes. The trend of the IGF-1 in fact, has a slope which is opposed to the IL 1ß, with a growth in values from T0 to T3. The analysis of the h-RANTES ChemoKines and the IL 8, having a chemioactive and activating action of the neutrophyls, has highlighted a decreasing trend from T0 to T3, which confirms the inhibiting action of the phlogosis factors by the Nd:YAG Laser.

Magnetic resonance

Via the MR the aim was to monitorise the morphological variations of the arthrosic knee treated with the Nd:YAG Laser. We initially tried to quantify any variations in the thickness of the incrustation cartilage of the femurotibial articulation.

The measurement of the thickness of the cartilaginous mantles was problematic with the bidimensional technique used due to the presence of numerous artefacts caused by the oedema often present in the surface strata of the cartilage.

It was easier to measure the cartilaginous ulcer. The images acquired in two dimensions of an arthrosic ulcer before and after treatment with Nd: YAG Laser were processed electronically and compared by measuring the maximum diameter and the surfaces.

In the case described a marked reduction was noted in the diameter and extension of the area affected by the ulcer.

We have judged these images with caution in view of the difficulties involved in reproducing with exactness the positioning of the limb examined. Nevertheless, the patient in question recorded a pronounced improvement in his clinical conditions with regard to both pain and functionality of the knee in question.

At the bidimensional MR follow-up six months after the treatment corresponding to two months after the end of the 2nd cycle, four out of the seven cases currently completed showed improvement and three were unvaried. The most evident improvements were in the reduction of the trabecular bone oedema and the cartilage, and in one case in the reduction of the extension of the cartilage ulcer.

In the aim of obtaining a more reliable and reproducible volumetric measurement of the cartilaginous lesions we considered it necessary to carry out a three-dimensional acquisition by means of the MR, in order to be able to measure with reliability, also in the control group, the region of interest according to the greatest axis of development.
As a whole, the magnetic resonance, despite its limits, seems to be the only technique capable of documenting the structural modifications of the cartilage.
Arthroscopy is not a viable method of screening in a clinical experimental trial for both ethical and technical reasons.
The ethical reasons are those related to an excessive invasiveness of the examination compared to the benefits and consequently it can not be considered as a basic investigation to be carried out on patients enrolling in a double blind trial.
The technical reasons that limit the use of the arthroscopy are linked to the fact that the acquisition of a photographic image depends in a specific manner on prospective factors that are difficult to reproduce in a second trial.
Yet arthroscopy is still useful to biopsic collection and therefore to assess the quality of cartilage. Considering that, we believe that it should be performed in few cases, after randomization of patients.
The study is still in progress even if we have a clinical protocol which appears effective, and we are reassured by the first results achieved. They indicate a clinical and functional improvement for every treated patient.

CLINICAL STUDY ON PATIENT

Moving from the experimental research and from the data of the preliminary study, we propose to perform a wider clinical study, in order to assess the chances of Nd:YAG Laser for the treatment of arthrosis.
We want now to begin a multicentric study which will allow us to collect a good number of cases with a double blind design.
To do that we asked for the collaboration of the "Fondazione Don Carlo

Gnocchi, Santa Maria agli Ulivi di Pozzolatico (FI)", and of "CONI" - Bologna of the "Servizio di Radiologia dell'Ospedale Nuovo di Imola (BO)". We will select from these operative units 100 patients affected by tibial-femural arthrosis, or patellar-femural arthrosis, age range 12-65. The selection method will be based on radiography assessment, since there is no reason to use a division based on arthroscopy. Radiography will be performed along the antero-posterior axis, under loading. Only patients affected by II and III stage arthrosis (which correspond to cartilage lesions showing a reduction of the joint space greater than 50%, and a mild bone wear, < 7 mm, respectively), following the Ahlback classification, will be admitted to treatment.

These patients will then undergo Magnetic Resonance with specific "weights" for the joint cartilage in order to confirm the presence and better assess the arthrosic lesions.
Images collected through this method will be then digitally elaborated in order to describe and, possibly, measure the qualitative and quantitative modifications of bone and cartilage components.

Then patients will undergo to *clinical tests:*
- W.O.M.A.C.: the Western Ontario and Mc Master Universities Index, functional clinical test specific for osteoarthritis
-2000 IKDC, test for subjective functionality assessment by the patient and objective assessment by the clinician.

V.A.S. quantitative scale for the assessment of pain *Lab tests:*
to assess possible metabolic alterations
VES, PCR, (1-glycoprotein, IL 1ß, IL 8, IGF-1, TGFß, h-RANTES)

Patients will be randomly assigned to 2 groups.
- A => will undergo a minimum power He-Ne Laser treatment (1mW)
- B => will undergo Nd: YAG Laser treatment daily for 21 dd.
Laser devices will be provided with their own software which will assign randomly patients to treatment A or treatment B. After six months treat-

ment (A or B) will be repeated. Every patients will be administered with a chondroprotective drug (galattoglucoronglycan sulfate800 mg/day).
Clinical tests will be repeated at the beginning and at the end of each of the two cycles. At the end, after twelve months from the beginning Magnetic Resonance will be repeated and the images collected will be compared with the previous one.
All patients will be assessed again after 12 months through the lab tests and by Magnetic Resonance again 10 patients, randomly chosen, will be assessed through arthroscopic biopsic collections.

THERAPEUTIC PROTOCOL
As far as the therapeutic protocol is concerned, Nd:YAG Laser will emit in pulse mode, with an average power approximatively equal to 9 W.
The total energy, 3000 J, will be divided in this way:500 J antero-lateral windows; 500 J antero-medial window; 500 J posterior-lateral window; 500 J posterior-medial window, 500 J medial patella; 500 J lateral patella, according to the individuated optical windows.

Performing this multicentric study we want to achieve important information about the clinical outcome after Nd:YAG Laser treatment, about the metabolic modifications of the treated osteoarthritis, and about the modification of the anatomic and pathologic conditions of the osteoarthritis treated lesions.
If the results achieved in vitro and on animal model were confirmed also on patients, interesting sceneries would open in osteoarthritis treatment, which would gain a new approach to improve effectively the quality of life.

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HILT vs TENS and NSAIDs:

A clinical study on low back pain from herniated inter-vertebral disk

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INTRODUCTION

The term back pain is used to indicate a clinical situation characterised by pain of the lumbar rachis that may irradiate to the buttocks or lower limbs.

This is a very common disorder: from 50 to 80 % of adults suffer from at least one episode of back pain during their lives [1]. In the United States it represents the primary cause of time off work; in epidemiological research carried out between 1984 and 1985, 14% of employees under the age of 45 lost one or two days off work for this reason [2]. The economical consequences from back pain in the United States fluctuate from between 16 billion and 50 billion dollars a year. According to the National Center for Health Statistics, the direct costs of back pain pathologies amount to $12,922,740,000 a year and indirect costs come to $ 2,950,020,000 [3].

One of the causes of back pain is herniated intervertebral disk.

This consists of a protrusion of the intervertebral disk into the bone marrow canal or the protrusion of a fragment of discal tissue outside the boundaries of the disk, with the consequent compression of the nervous roots [4]. This can be observed with greater frequency in patients of between 30 and 50 years with a ratio of 2:1 of males and females. The last two lumbar disks are the seat of the hernia in 90% of cases.

The natural history of the herniated intervertebral disk foresees a possible reduction in volume over several months: more voluminous hernias, and migrated or expelled hernias have a greater tendency to diminish in volume while this only occurs in 40% of contained hernias. The mechanisms via which this occurs are macrophagical phagocytosis and dehy-

dration of the herniate tissue. This evolution explains why the majority of back pain cases clear up spontaneously after several months, and also why it is opportune for the first-choice treatment to be of the conservative type in the majority of cases [5]. According to the North American Spine Society [6] in fact, in 70% of patients the pain is reduced or disappears with the conservative treatment. This type of treatment is recommended in the acute and subacute forms, as well as in the chronic forms [7].
Surgical treatment (mini-invasive or open section) must be reserved for cases that are resistant against conservative therapy or those which manifest motor deficiencies.
Within the field of conservative treatments the most common are drugs and physical therapy [8,9,10].
The guidelines of the North American Spine Society (NASS) [11] in 2000 recommend NSAIDs among the first in both the acute [12] and chronic phases [13,14], while the use of TENS [15,16] is recommended among the various physical forms. Nevertheless, for some time now the use of Laser therapy has become widespread. In fact, its anti-inflammatory [17], analgesic [18,19], and antiedemigenous [17] effects are well-known. Moreover, trials conducted in vitro by Repice [20] have demonstrated its neurotrophic powers as well. Finally, in bibliography trials have been conducted by Toshew [21] and Miriutova [22] which confirm the efficacy of Laser therapy in the case of back pain.
Our intention in this study was that of comparing three different therapeutic methods in symptomatological treatment of back pain from herniated intervertebral disk, testing their efficacy over time.
We compared NSAIDs (ketoprofen), with power Laser HILT and an electrotherapeutical method (TENS).

The trial was conducted in compliance with the Geneva Convention and the Helsinki Treaty. In particular, patients were required to give their written informed consent.

MATERIALS AND METHODS

Study population:

we selected 60 patients affected by symptomatic L4-L5 and L5-S1 EDD. The patients, who were all in the sub-acute phase, already showed symptoms from 1 – 6 months.

They were randomised into three groups of 20 patients each and every group was subjected to a different type of therapy:

- HILT;
- TENS;
- NSAIDs.

Therapies adopted:

HILT: Nd:YAG pulsed wave (pw), average power of 6 W, peak power of 1,000 W.

TENS: frequency 100 Hz, spike width 100 μsec.

NSAIDs: Ketoprofen.

Inclusive and exclusive criteria:

Patients who failed to give their informed consent were excluded from the study.

All patients were assessed with algo/functional clinical tests: Backill Test and VAS.The Backill measuring scale is an instrument that measures the severity of the symptomatology; it targets the rachis and assesses the pain and disability within the activity field of daily life. The score varies from 9 (severe painful symptomatology and severe disability) to 44 (absence of pain and full personal autonomy).

The VAS is an analogical-visual test which assesses the painful symptomatology. The score varies between un interval of 0 (absence of pain) and 20 (maximum pain imaginable).

We carried out controls (follow-ups) according to the following pattern:

T/1: at the end of the treatment lasting 15 days;

T/2: 45 days after T/0 (T/0: date of beginning treatment);

T/3: after 180 days.

Therapeutic protocols:

Scanning treatment	Level	Dose mJ/cm²	Accumulated energy
Therapy 1	10	460	500 joule
Therapy 2	9	560	500 joule
Therapy 3	8	610	500 joule

Table 1. *Values used in treatment with HILT*

Backill (9-44)	HILT	TENS	NSAIDs	ANOVA/*KrusW
T/0	26 ± 4,50	23,35 ± 3,34	23,10 ± 2,69	p=0.02
T/1	30,60 ±4,85	30,40 ±2,28	29,25 ± 2,07	* n.s.
T/2	32,70±4,61	25 ±4,69	22,85 ±2,64	p<0,0005
T/3	31,60±4,09	24,70 ±3,11	24,95± 4,30	p<0,0005

Table 2. *Statistical analysis among HILT, TENS and NSAIDs groups with respect to score obtained by the Backill scale at T/0, T/1,T/2 and T/3: One way ANOVA and Kruskal Wallis (*)*

HILT group: we carried out the treatment in manual scansion of the paravertebral region of the lumbar rachis at the speed of 1 cm a second.
Table 1 illustrates the values used in the therapeutic treatment.
The therapeutic cycle foresaw one session a day for a total of 10 sessions distributed over two weeks.
The TENS was applied with the method with 4 electrodes applied to crossed fields in the region concerned.
The therapeutic cycle foresaw 10 sessions (1/die) each lasting 30 minutes, distributed throughout 2 weeks.
The patients in the NSAIDs group were administered Ketoprofen at a dose of 100 mg/die, via os B.I.D., for 15 days.

Statistical analysis:
All continuous data are expressed in terms of mean and standard deviation of the mean. One Way ANOVA and Repeated Measure T test were performed to test the means hypotheses of respectively different groups and the follow up of single measure. When the Levene test for homogeneity of variances was significant ($p<0.05$) the Kruskal Wallis test was performed.
The Scheffe test and Mann Whitney test were conducted as post hoc to differences in study couples.
$p<0.05$ was considered as significant for all tests.
Statistical Analysis was performed by means of SPSS 7.5.

RESULTS

In Table 2 it can be seen how the HILT, TENS and NSAIDs all increase in the values of the Backill scores from T/0 to T/1. At T/2 instead, there is a different trend between the HILT, TENS and NSAIDs, seeing that the first continues to increase its values while the other two groups show a drop in trend that even continues until T/3 and involves all three groups. From the statistical analysis at T/0 a significant statistical difference is evident in relation to functionality, which indicates a lack of homogeneity between the groups (One way ANOVA p=0,02), while at T/1 the groups

Backill (9-44)	HILT	TENS	NSAIDs
T test T/0 vs. T/1	-4,60±4,38*	- 7,05±4,13*	- 6,15±2,23*
T test T/0 vs. T/2	-6,70±4,16*	-1,65±4,16	- 0,25±1,29
T test T/0 Vs. T/3	-5,60 ± 4,65*	-1,35±1,19*	-1,85±4,84

Table 3. *Statistical analysis with respect to the differences among Backill values at T/0, T/1, T/2 e T/3 in each group: T-test for paired data*

VAS (0-20)	HILT	TENS	NSAIDs	ANOVA/*KrusW
T/0	13,40 ± 4,37	13 ± 3,63	13,45 ± 3,90	n.s.
T/1	7,20 ± 3,09	7,40 ± 3,33	9,65 ± 4,27	n.s.
T/2	7 ± 3,23	11,50 ± 3,35	12,85 ± 3,44	p<0,0005
T/3	6,35 ± 2,43	10,90 ± 3,16	12,45 ± 2,98	p<0,0005

Table 4. *Statistical analysis among HILT, TENS and NSAIDs groups with respect to VAS scores at T/0, T/1, T/2 and T/3: One way ANOVA and Kruskal Wallis (*)*

VAS (0-20)	HILT	TENS	NSAIDs
T test T/0 vs. T/1	6,20±3,66*	5,60±3,56*	3,80±3,33*
T test T/0 vs. T/2	-6,40 ± 3,40*	1,50±2,21	0,60±1,53
T test T/0 vs. T/3	7,05 ± 3,41*	2,10±1,55*	1±1,78*

Table 5. *Statistical analysis with respect to the differences among VAS values at T/0, T/1, T/2 e T/3 in each group: T-test for paired data*

were all homogeneous. The picture changes radically at T/2 where the difference between the groups is extremely significant (Kruskal Wallis p<0,0005 and this tends also to be evident at T/3 (One way ANOVA p<0,0005). Also in reference to the Backill functionality test, table 3 illustrates the t-test relating to the difference between follow-ups (T/1, T/2, T/3) and T/0. By observing the table it is evident that the Laser group maintains a considerable difference with respect to T/0, while the other 2 groups show a sharp difference in T/1 and to a lesser extent in T/2 and T/3.

As far as the pain assessment test (VAS) is concerned, table 4 shows the values measured. The difference between the groups at T/0 and T/1 was not significant, while became very pronounced at T/2 (One way ANOVA p<0,0005) and T/3 (Kruskal Wallis p<0,0005).

Table 5 illustrates the values inherent to the analysis of the differences between the follow-ups and T/0. The behaviour of these therapeutic methods is very similar to that observed with the Backill test. In fact, the Laser maintains a net difference over time between the follow-ups and T/0, while for the other methods this difference is only recorded at T/1.

DISCUSSION

In accordance with the provisions in the NASS guidelines we decided to treat our patients suffering from herniated intervertebral disk with conservative and mini-invasive treatment.

Studies exist in literature that demonstrate the clinical efficacy of NSAIDs in treating back pain [23,24,25,26]. These drugs improve the clinical conditions of the patient with regard to their analgesic and anti-inflammatory effect. Unfortunately the analgesic and anti-inflammatory power of the drug is short-term and at times presents marked side effects with gastric bleeding of the mucosa and renal insufficiency in the elderly which means that it is necessary to limit its use to short periods (10-14 days).

The TENS has it rationale in Melzack and Wall's "Gate Control Theory" [27], in other words the use of sensitive stimulations for modulating the perception of pain. According to the authors [28,29], TENS is also responsible

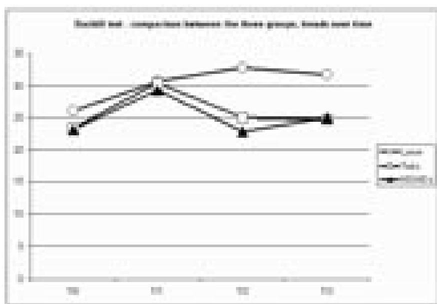

Fig. 1 *- Trend of mean scores obtained using the Backill test*

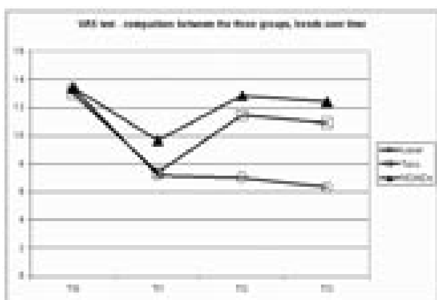

Fig. 2 *- Trend of mean scores obtained using the VAS*

for the increase in endorachis levels of endorphins.
The NASS recommends the use in the acute phase while there is no proof of its efficacy in chronic back pain [30].
Laser has been used in rheumatology for over twenty years with discordant results. Various types of lasers exist that differ with regard to their sources and radiation emitting powers.
In particular, other authors [31,32,33,34] in the past have resorted to Laser therapy for treating back pain. In previous experience however, CO2, GaAs, and GaAlAs lasers have been applied, as well as Nd:YAG but only for points. In this study instead we decided to use a HILT in scansion and not for points. These pulses are characterised by an elevated energy content, very high peak powers (kWatt) and low repetition frequencies capable of allowing the tissue to cool between one pulse and the next.
The objective of the study was that of comparing three different methods and evaluating the clinical effects over time (15, 45, 180 days). From the analysis of the results it is clearly evident that the HILT induces a better clinical response when compared to the other two methods, especially as it persists over time. In fact, the graphs in fig. 1 and fig. 2, which respectively describe the trend of the functionality and pain, clearly demonstrate a highly significant difference for the Laser that lasts over time with respect to the other two methods. In particular, a constant increase in the values can be observed up to 45 days for the functionality (Backill), which stabilises in the following months (third follow-up 180 days); better functionality in the part corresponds to an increase in values. The test that quantifies the intensity of pain (VAS), instead shows a reverse trend with respect to the functionality test: more intense pain corresponds to higher values. The graph in fig. 2 shows that when compared to other therapys, the HILT has a continuous decreasing trend. At T/1 the drop is similar to the TENS and NSAIDs groups while at T/2 and T/3 the trend is the opposite. Also by observing the difference (increase/decrease) between the various follow-ups (T/1, T/2, T/3) and the initial conditions (T/0), see tables 3 and 5, it emerges that the difference between the HILT therapy and the other methods turns out to be statistically significant in relation to the T/2 and T/3 follow-ups. At T/1, instead,

there are no significant differences recorded which testify to the fact that all three methods induce comparable anti-inflammatory, analgesic and antiedemigenous effects.
An apparently irrelevant point which should be considered is the lack of homogeneity between the groups recorded a T/0 with the Backill test, a lack of homogeneity that did not appear with the VAS. In our opinion this datum is not important seeing that in this type of study the acquisition of the absolute value is not important, but rather the analysis of the data in a relative sense. On the other hand, the reference interval of the Backill test varies between 9 and 44; the average difference recorded at T/0 between patients treated with HILT and those treated with TENS and NSAIDs is approximately 8.5%, and this difference is not very evident from a clinical point of view, which means that it is possible to consider the three groups as similar to each other.
At T/3 instead, this difference is equal to 20%, a value that also begins to be manifest clinically.

CONCLUSIONS

From an analysis of the results it appears that THE HILT induces a better clinical effect with respect to the other two methods being compared, not so much during the first period where the results are superimposable, but over time. In our opinion these results are encouraging and pave the way for organising clinical studies on a wide scale aimed at confirming this data. The reasons for which the clinical effects of the HILT are evident over time are not yet known so it is to be hoped that research will be carried out that aims at analysing these effects.

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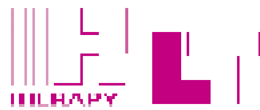

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Nd:YAG LASER

In the treatment of the lesions of the lateral ankle ligament

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Key words
ankle; ligaments; HILT; conservative approach.

ABSTRACT

Aim: assessing the results of the Nd:YAG laser treatment of the lesions of the ankle lateral ligament.

Introduction: few systematic studies are published about the effectiveness of the high-energy laser emission in sport traumatology.

Material and method: 15 athletes performing agonistic competitions, affected by acute (I grade) ankle lateral ligament lesions, were treated with high-intensity Nd:YAG laser HILT (10 subjects) or CO_2 laser (5 subjects). Patients were assessed for pain, swelling and articular function before treatment, after 1, 2, 3, 6, 12 weeks, and at final follow-up. .

Results: patients treated with high-intensity Nd:YAG laser HILT achieved faster pain and swelling resolution during treatment, and faster functional recovery, managing to return to agonistic activity earlier. The results achieved after 3 weeks of treatment are similar to the ones observed after 6 weeks in the control group.

Conclusions: the high-intensity Nd:YAG laser HILT has analgesic, anti-inflammatory, anti-oedema and bio-regenerative effects that can be observed clinically. In sport traumatology these effects accelerate the recovery time, and this is particularly useful for competitive athletes.

INTRODUCTION

Smaller muscular, tendineous and articular pathologies are very frequent events while practicing many sport disciplines. In the agonistic field, in particular, they need to be diagnosed soon and correctly, and they need to be treated effectively with a scarcely invasive approach to permit a fast recovery of the athletic activity. The interest that, in the last years, has

targeted the different sport disciplines drove the health system operators to use new therapeutic approaches, capable to accelerate the healing time for the different pathologies, thus reducing the recovering time of the athlete.
The Laser treatment was introduced in the clinical practice just for this reason. It consists in administering electromagnetic energy as an amplified and concentrated light radiation. There are many kinds of Laser devices that can be distinguished according to the active medium they use, the activation source or the optical resonator. The physical features of a Laser emission are defined by its wavelength, power and emission modality. As far as low and medium power Laser devices (such as Helium-Neon or Gallium Arsenide) are concerned, literature provides disagreeing data about their effectiveness (1). Among the high-energy Lasers, the CO_2 has a scarce penetrating power since water molecules absorb its wavelength. The Nd:YAG Laser emission, instead, is not absorbed by water molecules and has a good penetration power.
According to the pathology being treated, to the modality and the doses applied, the documented effects of the Laser radiation are the analgesic, the anti-inflammatory, the anti-oedema and the bio-stimulating ones. The analgesic effect seems to be both direct (on pain receptors) (2) and indirect (due to the production of endorphins locally and in the liquor) (3); the anti-oedema effect seems linked to the induction of dilatation of vessels (4) and to the activation of macrophages (5); the anti-inflammatory effect and the biostimulating one seem to be caused by a regulating effect on the membrane potential (6) mediated by specific chromophores (7,8).
The aim of the present study is to assess the effect of the Nd:YAG Laser HILT in the treatment of the lateral ankle ligament lesions in competitive athletes.

MATERIALS AND METHODS

We treated 15 competitive athletes affected by I grade external ligament lesion of the ankle.

Study group

10 on 15 patients were treated for 3 weeks with electrotherapy, massage, and Nd:YAG lasertherapy on alternate days (10 sessions). During the following 3 weeks they performed exercise with elastic bands, exercise bike, and did proprioceptive gym. Each lasertherapy sessions was divided in four applications:

1. 600 J, 1070 mJ/cm^2, 25 Hz
2. 600 J, 1170 mJ/cm^2, 25 Hz
3. 600 J, 1320 mJ/cm^2, 25 Hz
4. 600 J, 1430 mJ/cm^2, 20 Hz

During the first week treatment was performed on the external and internal perimalleolar areas; during the next two weeks only the anterolateral area was treated.

The features of the device used were: average power equal to 0.3-10 W, peak power from 200 to 3000 W, frequency from 10 to 40 Hz, diameter of the spot 0.5 mm.

The group of patients comprised 7 males and 3 females, average age 27.4. Average follow-up was 14.2 months (7-34 months).

Control group

5 on 15 patients were treated with the same protocol, with the exception of the laser being used (CO_2 instead of Nd:YAG). They were 3 males and 2 females, average age 33.8 years old. Final follow-up, on average, was 22.6 months (8-48 months).

Assessment criteria

The following parameters were assessed:

- Pain: measured according to a subjective scale from 0 to10
- Swelling: measured as the difference between the circumference of the non-affected ankle and the injured one

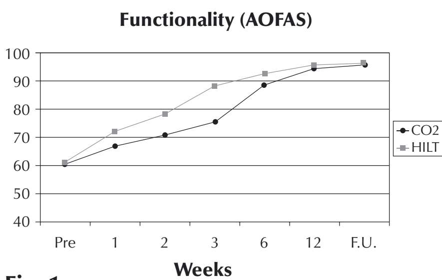

Fig. 1
Recovery of the articular functionality according to the AOFAS scale, during the treatment with Nd:YAG laser and CO_2 laser.

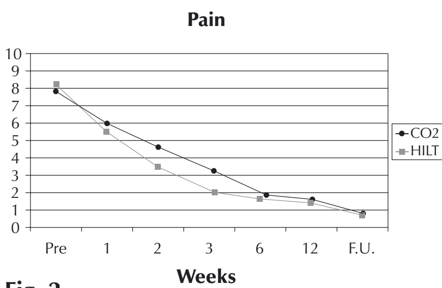

Fig. 2
Pain decrease during treatment with Nd:YAG and CO_2 lasers, assessed through a subjective scale from 0 to 10.

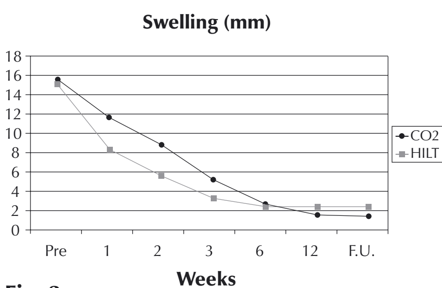

Fig. 3
Disappearing of swelling during the treatment with Nd:YAG and CO_2 lasers, measured as the difference between the circumference of the healthy ankle and the injured one.

- Functionality: measured according to the AOFAS criteria with a score from 0 to 100
- Number of weeks needed to recover competitive activity
- Occurrence of reinjury
- Permanence of subjective instability

All parameters were assessed before treatment, after 1, 2, 3, 6, 12 weeks, and at final follow-up.

RESULTS

Study group

The recovery to competitive activity was achieved in 8 cases; 1 patients recovered his sport activity but only at amateur level; 1 patient gave up any sport activity. The recovery to sport activity occurred, on average, after 5.3 weeks. We did not observe cases of reinjury, while functional instability, which was present after trauma in all cases, was present only in 4 patients at follow-up. 3 of them showed it only occasionally during sport activity.

Control group

The recovery to agonistic sport was achieved, in all 5 cases, after 6.6 weeks on average. We did not observe cases of reinjury, while functional instability, which was present after trauma in all cases, was present only in 3 patients at follow-up.

When we compared the study and the control groups, we observed a faster functional recovery (Fig. 1), a faster disappearance of pain (Fig. 2) and of swelling (Fig. 3). The progression of recovery was linear in the control group, while in the study group accelerated during the 3 weeks of treatment.

DISCUSSION

The set of selected patients was homogeneous, since they were all competitive athletes affected by grade I acute lesions. All patients were treated according to the same therapeutic protocol, with the exception

of the Laser being used, which was, therefore, the only variable of the study. The results show that the high-intensity Nd:YAG laser HILT is useful to accelerate the functional recovery of the injured athlete. This effect is due to its analgesic, anti-inflammatory, anti-oedema and bio-regenerative effects. Patients treated with the CO_2 Laser showed, instead, a linear improvement of their clinical conditions, that was similar to the one observed during spontaneous healing.

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Treatment of epicondylitis

Through HILT Therapy

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Key words:
epycondilitis, epicondylosis, tennis elbow, high intensity laser therapy

ABSTRACT
The aim of the present work is to assess the effect of a pulsed high intensity Nd:YAG laser therapy (HILT) on pain and functional recovery in athletes affected by epicondylitis. Subjects were 23 patients (9 white women and 14 white men), mean age 42, mostly tennis players, who were diagnosed persistent epicondylitis, lasting for more than 6 weeks, and who were already treated with other therapies. Each patient was treated for 10 sessions, once a day, except the weekends. Treatment outcome was assessed measuring the functional level, pain and the maximum isometric grasping strength of the hand at the beginning of treatment, after 5 sessions, and after the end of treatment. Functionality was measured according to the Steinbroker scale, modified for sport activity while pain was measured with the VAS scale. A significant reduction of pain symptoms was observed already after 5 treatment sessions, and further improvement was observed after 10 sessions. After 10 sessions, the grasping strength of the hand at the side affected by the pathology was significantly increased, on average, from the 66% to the 77% of the contralateral one.
HILT Therapy showed positive effects on pain and functionality in athletes affected by persistent epicondylitis. After comparing these results to the ones that can be retrieved in literature, anyway, it seems that this therapy gives no better results than other therapeutic methods, and, as it is for the alternative approaches, there are subjects not responsive to this kind of treatment. The structures affected by the pathologies are rather superficial, and the potentialities of this therapy, therefore, are not exploited at their best.

INTRODUCTION

The elbow is often affected by insertional disorders due to chronic or acute overload. The epicondylus more affected is the lateral one, and the term "epicondylitis" usually refers to both chronic and acute pathologies, which would be better described with "epicondylosis" [1,2], but the pathology is often named "tennis elbow", given the fact it often affects these sport players.

Typical pain at the lateral humeral condylus is caused by torsion or exceeding strain which lesion the extensor muscles of the wrist, whose tendons insert on the epicondylus; Muscles affected are, in particular, the short radial extensor of the wrist and, secondarily, the common extensor of fingers. In persistent cases, the most frequent pathological modification of tissues are the vascular proliferation, the hyaline degeneration, the proliferation of fibroblasts and calcifications[3]. Differential diagnosis assesses the neuropathies due to trapping of the radial or of the interosseus nerve, the osteochondritis of the radio-humeral joint, the lesions of the collateral ligament, and the cervical pathologies with radicular compression[4].

Treating such a disorder is difficult, even if it tends to disappear spontaneously, but athletes are particularly interested in shortening the healing time in order to achieve faster recovery of their sport activity. The therapeutic techniques used are many, comprising NSAIDS[5,6], corticosteroid infiltrations[7-11], ultrasounds[12], lasertherapy[18-20], and also transverse deep massage[11] and functional re-education through stretching and potentiation of the extensor muscles of the wrist [21,22], and, for more non-responsive cases, surgery[23-26].

In particular, infrared diodes lasertherapy (LLLT) showed to be scarcely effective to treat this pathology[27].

The aim of the present work is to assess the effect of a pulsed high intensity Nd:YAG laser therapy (HILT) on pain and functional recovery in sportsmen affected by epicondylitis

DEVICES AND METHODS

Subjects were 23 patients, 9 white women and 14 white men, practicing tennis, squash, golf, biking and motor biking (but mainly tennis players, see table 1), affected by diagnosed epicondylitis (pain on the lateral epicondylus when moving and after local compression; pain during hindered extension of the wrist and, sometimes, of the index finger) lasting from more than 6 months, and already treated with other therapies.

All subjects were treated with the ASA Nd-YAG Hiro 3.0 laser device, in the physiotherapy department of the Sport Medicine Institute FMSI in Turin, Italy. The laser source of this device produces a pulsed 1064 nm laser emission with 3kW peak power, and pulse duration < 120 ms; the average power is 10.5 W and the maximum fluency is 1780 J/cm^2. These features allow achieving a high penetration power in order to get both the analgesic action and the reparative stimulus.

During each session three treatment phases are performed:

1. initial phase: fast manual scanning (100 cm^2/30 seconds) with linear spot technique; treatment time is decided by the operator according to the area to be treated, up to 750 J in the whole;
2. intermediate phase: treatment of trigger points, if present, with short spot technique; treatment time is pre-settled and must not be greater than 7 seconds;
3. final phase: slow manual scanning (100 cm^2/60 seconds) with linear spot technique; treatment time is decided by the operator according to the area to be treated, up to 750 J in the whole.

The contracted muscles on the dorsal side of the forearm and the extensor muscles are treated. The arm is placed in pronation and slight flexion; fast scanning begins, treating the extensor muscles and then treating also the trigger points. Once muscles are treated, the insertion of the epicondylus is treated longitudinally and transversally. Treatment is then performed over the pain irradiation zone on the forearm and, if necessary, also on the volar face at the level of the flexor muscles of fingers and wrist, and on the antero-lateral face of the arm. Then the epithroclear zone is treated directly.

The intermediate phase is performed with the handpiece held still at 90° on the painful points, first on the muscular ones, then on the articular ones. The decrease or disappearance of pain is assessed and, if pain has not reduced at least by 70-80%, one more treatment is performed.
Treatment parameters:

- fluency 510 - 610 - 710 mJ/cm^2
- frequency level 10 - 9 - 8 (25 - 20 -19 Hz)
- total energy about 1500 J

Previously to HILT therapy treatment, each subject was treated with other approaches that had not given satisfying results: NSAIDS (87%), ultrasounds (35%), infiltrations (17%), mesotherapy (30%), shockwaves (8%). Subjects were asked to not use other therapies during HILT treatment, in particular analgesics and anti-inflammatory drugs.
Each subject was treated over 10 sessions, once a day except the weekends. During the sessions, both the operator and the patient wore the proper protective goggles. In case of particularly hairy subjects, the area to be treated was shaven.
At the beginning of treatment, after 5 sessions, and at the end of treatment the functional level was measured through the Steinbroker scale modified for sport activity:
0= sport activity possible without limitations
1= the most intense phases of the sport activity are limited
2= only moderate sport activity is possible
3= the subject can not perform any sport activity
Moreover the subject was administered the visual analogue scale (VAS), from 0 to 10, where 0 indicated absence of pain when moving the limb, and 10 indicated unbearable pain, which made moving the limb impossible.
The maximum voluntary strength of grasping with the hand was assessed, both at the affected side and at the contralateral[27] one, at the beginning and at the end of treatment.

sport	%
tennis	60,8
squash	13,0
motor biking	8,7
golf	4,3
alpinism	4,3
biking	4,3

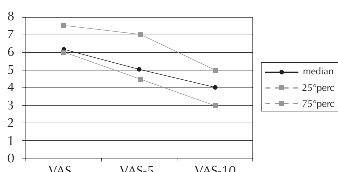
Table 1
Sports practiced by the treated subjects

Steinbroker class	beginning no.	after 5 sessions no.	after 10 session no.
3	15	13	9
2	8	8	11
1	0	2	3
0	0	0	0

Table 2
Distribution of the subjects in functional classes, corresponding to the assessments performed

VAS	beginning	after 5 session	after 10 sessions	P beginning-5	P 5-10
Median	6	5	4	<0.01	<0.01
25° percentile	6	4.5	3		
75° percentile	7.5	7	5		

Table 3
Median, VAS scale and 25° and 75° percentile at different assessment times. P significance of the difference.



Graph 1
Progression of pain as it was assessed by subjects through analogue scale before treatment and after 5 and 10 sessions of HILT therapy.

Statistical analysis was performed, for muscular strength data, through the t-test for paired data. Data not showing Gaussian distribution were analyzed with non-parametrical tests. In particular, the comparison among the 3 measures of the Steinbroker scale, and VAS, was performed through the Friedman test. If the test was significant (P<0.05) the comparison between pairs of data was performed through the Wilcoxon sign-test, and the correction of Bonferroni [28] was applied.

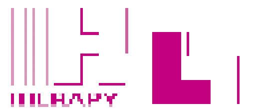
RESULTS

The average age of the treated subjects was 42, with a standard deviation equal to 9 years. The most practiced sports were tennis (61%) and squash (13%) (see table I).

If all treated subjects are considered, we can observe that initially 15 subjects (65%) were not able to perform any sport activity, and the 35% of them had more or less severe limitations (see table II). After 10 sessions, the subject who could not perform any sport activity had decreased to the 39%. We must observe, though, that after 10 sessions no subject can be regarded as healed. Moreover, the Friedman test does not show any statistically significant variation, at P<0.05, between the initial and final control.

If the subjective assessment of pain through the VAS scale is considered (see table III) we can observe a progressive reduction of pain. We provide the value of the median and not of the average since the distribution of data is not gaussian. The Friedman test for repeated measurements shows a significant reduction of pain symptoms at P<0.01. The Wilcoxon test, for the comparison between pairs of controls, shows that the reduction of pain is already evident after 5 sessions at P<0.01, and increases after 10 sessions. The trend in reduction seems constant; in fact, the difference between the assessment after 5 sessions and the final one is statistically significant at P<0.01 (see graph 1). No significant differences were observed between males and females, or between athletes practicing tennis or other sports.

The grasping strength of the hand on the affected side seems significantly reduced by the appearance of pain, if compared to the contralateral one



	Healthy side	Affected side before	after	P
	Newton	Newton	Newton	
average	530	348	406	<0,01
sd	130	113	118	
females	383	249	296	<0,01
	45	43	24	
males	625	411	476	<0,01
	54	97	98	

Table 4
Values of the isometric maximum grasping voluntary strength of the muscles of the hand, before and after HILT Therapy treatment (average, standard deviation and significance of the difference)

	beginning %	after HILT %	P
average	65.9	77.0	<0.01
sd	14.0	12.6	
females	66.1	78.4	<0.01
	14.8	11.4	
males	65.7	76,0	<0.01
	14.1	13.6	

Table 5
Values of the isometric maximum grasping voluntary strength of the muscles of the hand, given in percentage, before and after HILT therapy treatment (average, standard deviation and significance of the difference)

before beginning the treatment. The average reduction is 34% (348 N vs. 530 N, see table IV). The difference, given in percent, is similar in males and females (see table V). After the 10 HILT Therapy sessions, the strength is significantly increased ($P<0.01$), reaching the 77% of the contralateral one. The improvement in strength is similar between the 2 genders.

DISCUSSION

The age of the subjects does not correspond to the maximum sport activity, but it is the one when epycondilitis[2] can be more often observed according to the frequency and duration of the sport activity over previous years and to the fitness of the athlete. The prevalence of males reflects the greater diffusion of sport activity among people of this gender. This confirms the overload cause typical of this disorder. This pathology, as other insertional pathologies, tends to heal spontaneously. Healing time can vary from 2 weeks to 2 years. Therefore we have excluded from this study subjects showing recent onset of the pathology, since this would have required a placebo control group. Instead we considered subjects showing symptoms for more than 6 weeks, who where already treated with other therapies without significant results. Doing so, improvement observed after one week of HILT treatment can be only an effect of HILT therapy. Nonetheless, we should underline that 10 sessions, in 2 weeks, were not sufficient to give complete healing, but only pain and functional deficit reduction. The improvement of the functional deficit is evident when the isometric strength test is considered, but not according the modified Steinbroker classification
This classification, anyway, can be hardly applied in some cases, since subjects showing the most evident symptoms (class 3) are forced to drop sport activity and, even if pain is reduced, they do not feel confident in beginning the activity again, since they fear an increase in pain, especially if this fact had already happened previously. This scale seems useful, therefore, to define the initial stage of the pathology and not to assess small improvements. The measure of the grasping strength of the hand (grip test), on the other hand, does not concern directly the muscle that is more often affected by the pathology, that is the short

radial muscle of the carpus. The test was chosen since it is simple, the device to perform it was available, and has been already used in other published studies[27,29-31]. The grasping strength applied is not always correlated to a functional deficit in sport activity, but we believe that the modifications over time, with respect to an initial value, can be linked to the variation of functionality of the limb, beyond the pain sensation assessed by the subject through the analogue scale. Therefore, the Steinbroker scale indicates an initial deficit, while the grip test is more sensitive to variations over time, either spontaneous or therapy-induced, as in our case. The average increase of the grasping strength we observed after 10 HILT therapy sessions is greater than the one observed by Basford e al[31] but smaller than in Benjamin e al[32].
Some Authors who applied low energy lasertherapy observed positive results. Tam [33] reports results spanning from good to very good both for tendonitis and epicondylitis. Vasseljen[17] achieved an improvement in 47% of subjects affected by tennis elbow. We achieved an improvement according to the Steinbroker classification in the 35% of subjects, a 5% increase in grasping strength of hand in 65% of subjects, and a 2 points pain reduction in the analogue scale in the 83% of subjects.
Therefore, the results observed after the application of HILT therapy appear similar, or slightly better than the ones achieved with other laser emissions. On the other hand the structures affected by the pathology are rather superficial, and do not require deep penetration of the laser energy. The trend of the VAS score, see graph 1, does not show any variations in slope, and this suggests that a greater number of sessions (15 to 20) should be performed in those cases that do not respond to treatment. In fact, as it is true for all the therapies addressing epicondylitis, there are some non-responsive subjects. We cannot say *a priori*, by our data, which these subjects are. This is possible only after 10 sessions. We observed, in fact, that 5 subjects (22%) who did not show any pain reduction after 5 sessions, improved after 10 sessions.

CONCLUSIONS

HILT therapy showed positive effects on pain and function in subjects practicing sport activities, affected by persistent epicondylitis. Comparing our data with the published ones, it does not seem that this therapeutic approach has effects significantly greater than other therapeutic methods and, as it is true for other approaches, there are not-responsive subjects also for HILT treatment. It is difficult, therefore, to suggest which treatment should be applied first, and we leave the choice to the specialist or to the physiotherapist. Whether HILT therapy is chosen as a first or second approach we advise, also to treat epicondylitis due to sport activity, to follow a scheme comprising the use of a tutor and the application of static stretching[1-2].

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Carpal tunnel syndrome:
HILT Therapy treatment

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Key Words:
Carpal Tunnel Syndrome; Physical Therapy, Lasertherapy, Echography, Electromyography

ABSTRACT
The aim of the present study is to assess the effectiveness of HILT laser treatment for carpal tunnel syndromes. It's a very widespread pathology that has many different etiologies. Its typical symptoms are the ones of the entrapment of the median nerve at the wrist, that is to say paresthesias and pain at wrist and hand. Diagnosis is based on the clinical framework, but above all on the finding of alterations of the nerve conduction, assessed through EMG.
At the present time, treatment is based on general and local medical therapy, on physical therapy and on the surgical decompression of the nerve. As far as physical therapy is concerned, there is scarce evidence about its effectiveness.
In the present study, 25 patients affected by mild or medium-level carpal tunnel syndrome underwent HILT laser treatment and were assessed through clinical, echographic, and EMG tests. Assessment was performed before and after treatment, and 3 months after its end.
The study shows that this physiotherapy method has a good effectiveness in the treatment of carpal tunnel syndrome.

INTRODUCTION
Carpal tunnel syndrome (CTS) is certainly the most frequent syndrome caused by nerve entrapment, i.e. those pathologies caused by the compression of a nerve that passes through small openings or channels whose walls are rigid. It is caused by the compression of the median nerve at the level of the carpal tunnel, a bone-fibrous channel of the wrist where, beyond the median nerve, also the nine tendons of the

common flexors of fingers and thumb are located.
Causes can be many. The most frequent are repetitive traumas or micro traumas, carpal bones anomalies, the thickening of the carpal transverse ligament, the finger's flexor tendons tenosynovitis, and the intra-channel oedemas and haemorrhages (1-2). Often these causes are due to functional overload of the wrist, because of repetitive job activities (3-4-5). Typical symptoms are night paresthesias to the first 3 fingers and to half of the 4th finger of the hand. Pain can irradiate also to forearm and arm. In more advances stages, paresthesias become persistent also during the day, and are often associated to hypoesthesia, pain to the intrinsic muscles of the hand at the thenar eminence.
Unfortunately the clinical semiology of the carpal tunnel syndrome is quite scarce: it is based essentially on the search for local phlogosis signs, in particular at the level of the flexor tendons of the fingers, on the articular limitations, on the assessment of the strength and sensitivity and on two semiological fundamental tests, which are the Tinel and the Phalen sign (3-6). The confirmation of the diagnosis is, anyway, given by instrumental tests such as the electromyography (7-8) and the muscle-tendon echography at the wrist (2-9). The comparison between clinical and instrumental data is just what allows defining prognostic criteria for a possible recovery, such as for a reasoned therapeutic path (4-10).
The common opinion is that non-surgical treatment of CTS can give only a temporary relief, while surgery to decompress the nerve is the only resolutive therapy. Actually, if a correct clinical-instrumental framework is achieved, lesions classified at stage I, II and III (table 1) can be treated through a conservative approach, since the anatomical damage is reversible. Such approach is based on the systemic medical therapy, the local-regional infiltrative therapy, the immobilization or – in any case – the reduction of the mechanical stress, and finally the physiotherapy treatment. As far as the last one is concerned, the resolution of pain and of the symptoms related to nerve suffering can often require many months. The international literature shows that the only physical therapies that were scientifically effective in treating CTS are ultrasounds (11) and ionophoresis (12). For all the other therapies results were declared, but

not supported by an adequate scientific documentation.
The aim of the present work is to assess the effectiveness of HILT laser therapy to treat all the CTS that fall in those reversible clinical conditions we spoke of before, and to document the possible clinical and instrumental improvements.

MATERIAL AND METHODS

25 subjects, 17 women and 8 men, age between 32 and 56 (average 42) were assessed. They presented a mild or medium level carpal tunnel syndrome that, according to the echographic and EMG tests, could be classified into the first three levels of seriousness. 19 subjects showed monolateral symptoms while the remaining 6 subjects showed symptoms at both sides. Among the 17 women, 8 were housewives while the remaining 9 and all the males did a manual job (metalworkers, weavers, slaughterers). (Table 2).
Inclusion criteria for this study were the presence of clinical symptoms suggesting the CTS for at least 3 months, and the finding of EMG alterations compatible with a low or medium entrapment of the median nerve at the wrist (positivity of comparative tests, showing the speed of sensory conduction at the second tract between finger and wrist has decreased, with or without an alteration of the distal motor latency). The seriousness of the electrophysiological framework has been classified according the criteria of the American Association of Electrodiagnostic Medicine (table 3.). During the treatment period and the follow up, subjects included in the present study did not follow any other physical therapy and took a pain killer (paracetamol) only occasionally. The device used in this study was a HIRO 3.0 laser device by ASA srl, Arcugnano (Vicenza – Italy). It's an high intensity Nd:YAG pulsed laser. Peak power is equal to 3 KW, and the maximum energy for each pulse is 350 mJ; the average power is 10.5 W, the fluence is 1780 mJ/cm^2, and the duration of each pulse is less than 120 microseconds. The treatment was performed with a standard handpiece for pain therapy, provided with a fixed spacer. The diameter of the lighted spot was 5 mm.
According to the experimental protocol, patients underwent a clinical

assessment before the beginning of the laser treatment (T0), at its end (T1) and after 3 months (T2). Clinical evaluation excluded all the pathologies affecting proximal districts (cervical column, shoulder, elbow) that can irradiate symptoms to the wrist and the hand. Parameters assessed were:

- the entity of pain measured through the Visual Analogue Scale (VAS)
- the active and passive articular range of motion of the wrist (palmar and dorsal flexion, ulnar and radial side deviation, prono-supination), assessed trough a semi-quantitative scale (N: normal; LR: slightly reduced – max. 20%; R: reduced)
- the strength of wrist and fingers (conventional scale 0-5)
- specific tests for the CTS (Tinel and Phalen)
- sensitivity test (pain, tactile, 2 discriminating points)

Beyond clinical evaluation, according to the study protocol an echographic assessment of the wrist was performed with an electronic linear probe at 9 MHz before the treatment (T0), after it (T1) and 3 months after (T2). Pathological findings were:

- presence of oedema (hypoechogenicity) of soft tissues
- phlogosis of the tendon sheaths of the carpal flexors
- signs of compression of the median nerve, together with an increase of its proximal diameter (> 4 mm)
- thickening of the transverse carpal ligament (> 0.6 mm)
- presence of external compressive factors (tendon cysts, malformations of the bone channel, new formations)

As far as the comparative study of the EMG results, measurements of the speed of sensory conduction (SSC) between the II finger and wrist, and the distal motor latency (DML) were performed before treatment (T0) and 3 months after its end (T2). The electrophysiological data were considered pathological when:

- DML of the median nerve was equal or greater than 4.4 msec

- DML of the median nerve was greater at least by 1.4 msec than the one of the ulnar nerve of the same side
- Orthodromic SSC if the median nerve in the II finger-wrist tract was lower than 44 m/sec
- Sensitive latency of the median nerve in the II finger-wrist tract was greater than 3.4 msec
- Sensitive latency of the median nerve in the II finger-wrist tract was greater by 0.7 msec than the one of the ulnar nerve of the same side.

All patient underwent 10 treatments with HILT laser therapy. Sessions were performed daily for 5 days a week, following a standard protocol of 3 treatment phases for each session:

- initial phase: fast manual scanning (100 cm^2/30 sec) on all the volar surface of the wrist and on the zone of distal and proximal paresthesic irradiation, until reaching 500 J as a total energy dose;
- intermediate phase: short spot technique on the local and regional trigger points, until pain attenuates by 70-80%, avoiding direct application on the median nerve;
- final phase: slow manual scanning (100 cm^2/60 sec) by linear spot technique, on the same areas which were treated in the initial phase, until reaching 500 J as a total energy dose.

The initial and final phases of treatment were subdivided in 3 steps; fluence applied was respectively 510, 610, 710 mJ/cm^2, frequency was 25, 20 and 19 Hz, total energy administered was approximately 1000 J. Results of the study were analyzed statistically through t-test for two data sets, assuming different variances, for parametrical data (VAS and strength of fingers and wrist) while descriptive or semi-quantitative data were analyzed through a t-test for the comparison of two percentages based on large-sized data sets, comparing data at T0, T1, T2. Significance threshold was set at $p<0.05$.

RESULTS

Results concerning the clinical and instrumental variations at T0-T1-T2 time are summarized in Table 4 and significance for all comparisons is showed in Table 5. Pain levels, measured through the Visual Analogue Scale (VAS 0-10), was 7.2 at T0, 3.9 at T1, and 3.4 at T2. Variations at T0 vs. T1 and T0 vs. T2 were highly significant ($P<0.001$). Sensitivity alterations, such as paresthesias and tactile dysesthesias, were present in 22 over 25 subjects before treatment while, after its end, they were present only in 14 cases. At 3 months follow up 13 subjects over 25 complained about the persistence of sensorial disorders. This variation was nearly significant in the T0 vs. T1 comparison, and was significant comparing T1 vs. T2 ($p<0.01$).

As far as the articular range of motion of the wrist is concerned, active mobility improved more than the passive one. In fact, while subjects showing normal active mobility at T0 were 13, this number increased to 19 and 20 at T1 and T2 respectively, as it is shown in the summarizing table. At the same time, the number of patients showing a partial limitation of mobility decreased from 3 (T0) to 2 (T1) to 1 (T2). This variations were at the significance limit ($p<0.05$). Passive articular range of motion was unchanged, and the minimal differences observed among T0, T1, and T2 were not significant. As far as strength is concerned, the average value improved for the wrist, which increased from 3.4 (T0) to 3.9 (T1) to 4.1 (T2), while the fingers' strength increased from 3.2 (T0) to 4.1 (T1) to 4.3 (T2). These variations, according to the t-test were highly significant ($p<0.01$ for the comparison between T0 and T1 regarding the wrist's strength; $p<0.001$ for all the other comparisons).

Both the carpal tunnel syndrome specific semiological signs, Tinel and Phalen, improved. The first was positive for 23 subjects over 25 before treatment, while after therapy it was positive for 16 subjects, and at the follow up (T2) for 15 of them; the second one was positive for 21 patients at T0, for 13 patients at T1, and for 11 patients at T2. For both signs the variation is at the significance limit in the comparison between T0 and T1 ($p<0.05$), while is highly significant for the comparison between T0 and T2 ($p<0.01$).

Echographic examinations showed a clear improvement of the signs referring to phlogistic conditions of the soft tissues of the volar compartment of the wrist, mainly of the flexor tendons: in particular, oedema of soft tissue, which was present in 21 subjects before treatment, was affecting 14 subjects after treatment and only 8 subjects at T2. Statistical analysis showed a variation at the significance limit for the comparison between T0 and T1 ($p<0,05$) and a very high significance in the comparison between T0 and T2 ($p<0.001$).
The phlogosis signs of the flexors (distension of the sheaths) reduced from 9 to 4 to 3 respectively at T0, T1, T2, with variation at the significance limit for the comparison between T0 and T2 ($p<0,05$). No significant variations regarding the thickness of the transverse carpal ligament were observed.Electromyography data collected before treatment showed alterations of the sensory conduction in all the subjects studied, while 14 subjects showed also altered motor conduction. Assessment at T1 was not performed, according to the protocol, since variations of the electrical conduction of the median nerve need medium or long time intervals to show, and so repeating the tests just after the end of the therapy had no sense. At the 3 months follow up, instead, sensory conduction was altered in 18 patients, and motor conduction was altered in 12 patients, over 25 total subjects. The variation between T0 and T2 was significant for the sensory conduction ($p<0.01$) while the one concerning the motor conduction was not significant.
The above-mentioned neurophysiologic parameters allowed us to classify the seriousness of the carpal tunnel syndrome according to the AAEM criteria. Before treatment 11 and 14 patients showed mild and medium level carpal tunnel syndrome respectively. No one of them showed initial (minimal) or severe alterations. At 3 months, 7 subjects showed minimal (initial) alteration, 6 subjects showed a mild alteration and 12 subjects showed a moderate alteration. Part of the patients, in other words, passed from more severe to less severe classification. This variation was numerically more evident in the passage from the moderate to the initial category, and was therefore linked to the variations of the sensory component, and it was higly significant ($p<0,01$) (see Figure 1).

DISCUSSION

Even if data regard a small number of patients, 25 subjects, and should be confirmed by studies on a greater number of subjects, we observed that there was a clear improvement in some fundamental clinical parameters typical of the carpal tunnel syndrome, such as pain, sensitive disorders, and also the strength of the hand.
If single cases are analyzed, those undergoing the best clinical outcome are also the ones that showed a more consistent reduction of inflammatory signs through echography. This shows that HILT laser treatment has an immediate effect on the local and regional phlogosis component.
In some cases we noted that, even if the reduction of the phlogosis indexes was absent or scarce, a discrete reduction of pain and paresthesias could be observed, thanks to the direct action of the HILT therapy on the nervous component.
Also as far as neurophysiologic data are concerned, variations concerned mainly the sensory conduction, which is the first one being affected in case of nerve sufferance, and it is also the one showing a greater recovery possibility. In the more compromised clinical cases, where also the motor component was affected, we did not observe any relevant variations. The results we achieved are suggestive, and seem to indicate that in the initial phases of the carpal tunnel syndrome, when the suffering of the median nerve is caused mainly by the local and regional phlogosis, there is a good possibility of recovering through the HILT treatment. This underlines the fact the prompt and early intervention is necessary.

CONCLUSIONS

This study shows that HILT laser therapy can be considered a valid approach to the treatment of the low and moderate level carpal tunnel syndrome, above all in those situations where plain phlogosis signs are present.
Results achieved after treatment remained stationary or even improved at the 3 months follow up.
The most significant result is that we managed to observe that there was a clear correspondence between the clinical improvement, which is mainly subjective, and the instrumental improvement, testified by the results of the echographic and neurophysiologic tests.

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Table 1: assessment of the stage of the pathologies of the wrist-hand district

Stage	Echographic findings	EMG findings	Anatomical damage	Seriousness
I	Slight oedema (hypoechogenicity) at one of the affected districts	Minimal channel pathology	Reversible	Initial
II	Oedema (hypoechogenicity) at one of the affected districts	Mild channel pathology	Reversible	Mild
III	Severe oedema at one of the affected districts	Medium channel pathology	Reversible	Medium
IV	Tendinosis or fibrosis or tendon rupture or surgical correction of the tendon pathology	Severe channel pathology	Irreversible	Medium-severe
V	Tendinosis or fibrosis or tendon rupture or surgical correction of the tendon pathology	Severe channel pathology	Irreversible	Severe
VI	Tendinosis or fibrosis or tendon rupture or surgical correction of the tendon pathology	Severe channel pathology	Irreversible	Very severe

Table 2: subjects

	Number	Average age	Stage			Side		Working activity	
			I	II	III	Monolateral	Bilateral	Housewife	Manual jobs
M	8	45	-	3	5	6	2	-	8
F	17	38	2	7	8	10	7	8	9

Table 3: electrophysiological classification of the CTS (AAEM 2002)

Entity	EMG Findings
Negative	Normal to all tests
Minimum	Anomalies only at comparative tests
Mild	Altered speed of sensory conduction (SSC) finger-wrist. Distal motor latency (DML) normal
Medium	Altered SSC, altered DML
Severe	SSC absent, altered DML
Extreme	No sensitive or motor answers

Table 4: results.

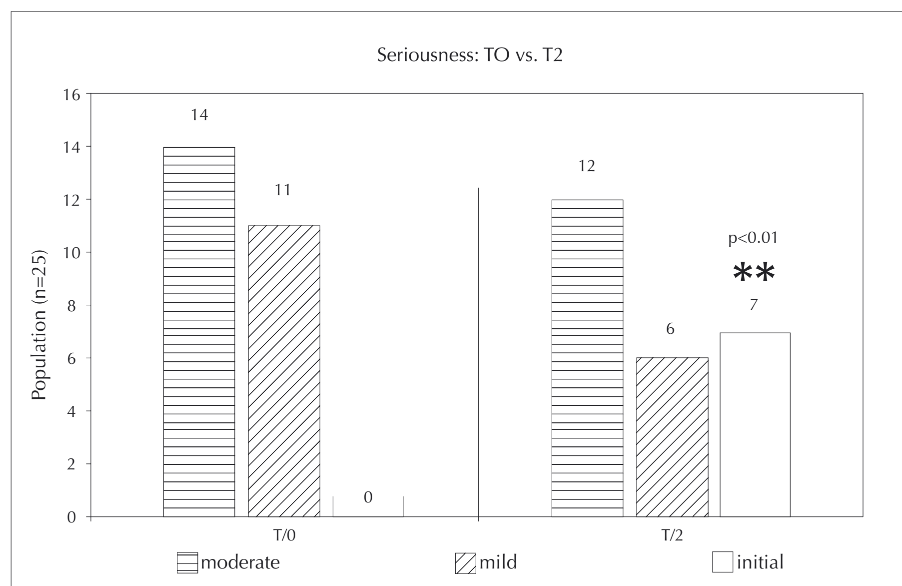
	Pain (average value)	Sensitivity alteration	Articularity						Strength (average value)		Positivity to Tinel sign	Positivity to Phalen sign
			Active			Passive			Wrist	Fingers		
			N	LR	R	N	LR	R				
Time 0	7.2	22	13	9	3	16	7	2	3.4	3.2	23	21
Time 1	3.9	14	19	4	2	17	6	2	3.9	4.1	16	13
Time 2	3.4	13	20	4	1	17	6	2	4.1	4.3	15	11

	Echography				EMG		Seriousness		
	Oedema	Tendon phlogosis	Nerve compression	Thickening of transverse ligament	Alteration of SSC	Alteration of DML	Initial	Mild	Moderate
Time 0	21	9	-	7	25	14	-	11	14
Time 1	14	4	-	6	N.V.	N.V.	N.V.	N.V.	N.V.
Time 2	8	3	-	6	18	12	7	6	12

Table 5: significance of all comparisons

Test Clinico	p<
Initial seriousness T/2 vs T/0	0,01
Sensibility alteration T/0 vs T/1	0,05
Sensibility alteration T/0 vs T/2	0,01
Active articularity N T/0 vs T/2	0,05
Tinel sign positivity T/0 vs T/1	0,05
Tinel sign positivity T/0 vs T/2	0,01
Phalen sign positivity T/0 vs T/1	0,05
Phalen sign positivity T/0 vs T/2	0,01
Oedema T/0 vs T/1	0,05
Oedema T/0 vs T/2	0,001
Tendon phlogosis T/0 vs T/2	0,05
SSC alterations T/0 vs T/2	0,01

Figure 1: comparison of the electrophysiological seriousness (AAEM)



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