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Guide for Authors.

Key words: Disturbance; error or inaccuracy; deterministic physics; probabilistic physics; field concept; field propagation.

Physical grounds for understanding the interaction between electromagnetic fields and biological objects: inaccuracy and fields.

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The present paper represents the first of two contributions. This first paper will discuss some of the basic physics issues, in particular some of its applications to biology and medicine. We will essentially cover measurements, disturbances, measurement errors, probability and field concept. In the second paper we will discuss about electromagnetic fields interactions (from electric fields, to magnetic fields and finally coupled electromagnetic fields) with biological materials.

I) MEASURAMENT AND DISTURBANCE: THE PROBLEM OF INTERFERENCE AND VARIATION (FROM A PHYSIC AS WELL AS MEDICAL POINT OF VIEW)

a) "static" disturbance.

b) "dynamic" disturbance.

c) the variation interval of the classical result, that is the classical measurement inaccuracy.

d) the variation interval of the quantum

result, that is the quantum measurement inaccuracy. **e)** conclusion.

Every measurement needs an interaction with the system to be measured and this interaction disturbs the system. As a consequence, the result obtained is not only linked to the quantity to be measured, but also to the disturbance caused. Despite, the fact thet measuring device is chosen to have as little disturbance as possible, it is impossible to completely abolish it, as it is in the nature of things. The following two examples will try to illustrate what reported earlier, choosing extreme circumstances in order to explain the problem better.

a) "static" disturbance.

Disturbance can be "static" or "dynamic". Let's consider first of all a body temperature measurement. The instrument used will be the classical clinical thermometer, containing a substance dilating with the increase in temperature. Assuming that the thermometer is very cold, for example because it was kept in the fridge before the measurement was taken, a certain amount of body heat will be necessary to bring the thermometer at the same temperature of the armpit. At the same time the armpit will cool a bit. The end result is that the temperature measured would be slightly less than the "real" armpit temperature, that is the temperature that would have been obtained if the thermometer was not kept in the fridge. The real reason for this discrepancy is that every measurement represents a disturbance of the system that is measured.

b) "dynamic" disturbance.

Let's now consider an example of a "dynamic" disturbance. Blood pressure measurement can be considered as an example for the clinical field. Obviously, blood pressure is a well defined physical quantity to be measured. The sphygmomanometer's display will certainly indicate a pressure value. Also in this case, two different pressure measurement methods can give different results because of the greater or smaller interaction, or disturbance, with the system. However, this is the measurement of blood pressure. The definition of the maximal (systolic) and minimal (diastolic) points of the measurement is linked to the onset or disappearance of tones and noises. We will spare the concept of contemporaneity that does not certainly represent a problem for this classical physics case (even if Einstein would have doubted it). There is however, the problem of the instrument that perceives the tone or the noise. Therefore, there is a second issue concerning the fact that two physical quantities need to be measured at the same time. Even in this case the final measurement must correspond to the value (of the equilibrium state) that the new set, composed by the old system and the measurement device, will have obtained.

However, there is also the problem concerning the blood pressure temporal evolution to be considered. When measuring a length, this is expected to be constant in time (weather measured with a carpenter measuring tape of with a high precision instrument). In reality we all have heard about concepts (or experiences) such as thermic dilation of objects, for example of rail tracks. We would not expect this phenomenon to happen in the matter of few minutes and with virtually constant temperatures, but only after an adequate period of time and in the presence of a high thermic gradient. On the contrary, blood pressure can change very rapidly and without considerable temperature variations. The variation is mainly due to molecular mechanisms, in particular to the secretion and (rapid) action of hormones such as adrenalin. This is why in this second example the time when the measurement is taken must also be accounted for.

Finally, the initial concept can be applied to this case: measure = system disturbance. If the system is "inanimate" we will only have a physical disturbance. But if the system is "animated", that is if the quantity to be measured is biological and directly linked to biological mechanisms, the disturbance will be not only physical but also biological. Therefore, the quantity measured, will be affected not only by the physical interaction but also by the biological feedback.

c) the variation interval of the classical result, that is the classical measurement inaccuracy.

Certain measurements are made of few "steps", or sub-experiences that converge in the final measurement. This can be preceded by a certain number of chemical reactions. Following all these steps the result will be extremely variable. This is well known for one of the simplest blood measurement, the level of glucose or glycaemia. Even if this is not an "animated" system, the steps required are multiple and lead to a relatively high variability. In other words, if the measurement is repeated on the "same" blood several times in a row, the result would probably not be the same and the difference can be as much as 10%. In physics this is called measurement error theory even if it should be called measurement inaccuracy theory.

d) the variation interval of the quantum result, that is the quantum measurement inaccuracy.

To simplify the question, at atomic and subatomic level (or nuclear level) the classical physics rules, or Newton physics, are no longer valid. Instead, quantum physics rules apply; these were elaborated in the 1930s by several European physicists including Heisenberg and Schroedinger. What is of particular interest is that, like the name suggests, measurement results do not vary continuously, but they assume only certain values, discrete or quantized. However, the interaction can modify the system and, therefore, the measured result can be different from the "real" result.

Quantum physics is not only a discrete and quantized values physics, but it is also a "probabilistic" physics. Contrary to classical physics, that is "deterministic", quantum physics rules allow us to do only forecasts, or to express/foresee the probability to find or measure a certain result. This concept causes the fact that we cannot be "sure" of the result of a single measurement. In this field it is necessary to repeat a measurement several times and use the means or even better the distributions. If for example, three different results a, b and c are found, the best thing is to do is to calculate how often (expresses as percent) each a, b, and c value was found.

e) conclusions.

These outlines were aimed at highlighting something fundamental but not obvious. When we think about a measurement, for example weighing an object, it is common sense that repeating the measurement several times with the same instrument, for example the same scale, we will obtain the same result, unless the scale has been tampered with. Obviously, changing the scale we expect that results may be different (in the theory of the measurement inaccuracy, this is called systematic error or inaccuracy).

However, measurement means, as stated above, interaction with the system to be measured and therefore a disturbance of the system itself. In addition, the problem of the measurement inaccuracy (or error) must be considered. This inaccuracy determines that the result of a measurement might be different from the following one. This inaccuracy or indetermination can become "dramatic" in the case of microscopic quantities measurements, at atomic or subatomic level. In this case we can often determine only the probability that certain results will be found.

Now the question is: what's the importance of these considerations on the interactions between electromagnetic fields and live matter? The answer can be summarised as follows: the reasons for these interactions are based on numerous experiments. On one side it is therefore important to understand that the results of these experiments are numbers subject to errors. Moreover, with molecular biology, the tendency is towards extremely small measurements. At these levels, quantum effects may also play a role, making measurement understanding even more difficult.

II) THE (PHYSICAL) CONCEPT OF FIELD, IN PARTICULAR OF ELECTROMAGNETIC FIELD.

a) physical quantity = measurable.

b) spatial region properties

(can be measured indirectly).

c) wave-corpuscle dualism.

The concept of "field" has many meanings, and not only in the Italian language. In the Italian Dictionary (Istituto dell'Enciclopedia Italiana, Roma 1986) there are six main meanings for this word, each of them with four or more secondary meanings for a total of 25 different definitions. It is interesting to notice that the first meaning contains the surface unit of measurement, that is a typical physical quantity, used in particular in the region of Venice era, with different values. It is the fifth meaning, the scientific one, which ranges between many scientific branches. It varies between the concept of "field" in the set theory to the one defined in algebra ("field" is an algebraic structure), and finally the IT meaning (field is a selection of data that makes a record), that is probably the most recent meaning.

But it is in physics that the concept of "field" finds a wide deployment, from the gravitational field to the temperature field and of course the electromagnetic field.

a) physical quantities = measurable.

Let's not forget that all quantities that have a meaning in physics are observable and measurable. In reality the same applies for all experimental sciences. For this purpose we can use the old joke that the sex of angels has no meaning in physics because it cannot be measured. In reality this is less strange than it might seem. In fact, as a geneticist explained to me, there are at least 10 different ways to define sex in genetics. Without complicating things too much, we must remember that in genetics, as well as in physics, there are situations where the details about the type of measurement needs to be specified. For example, the calculation of the nuclear radius includes several types of measurements (indirect); therefore, the type of measurement used to measure the X nucleus radius must be specified.

b) spatial region property (can be measured directly or indirectly).

A long dispute has been going on for the last two hundred years about the definition of electromagnetic and electrical fields as physical quantities. The problem was, and still is, linked to the fact that a physical quantity must be measured directly. A length can be directly measurable, as can a force, while a field might not be. As everybody has learned at school, an electrostatic field is equal to the force divided by the electric charge, in other words is a force per charge unit. We will not enter into the discussion of John Jackson, a great scholar or classical electrodynamics of the 20th century. In his treatise, on Classical Electrodynamics he pragmatically declares that "even if the quantity that is being measured is the force, it is useful to introduce a concept that disregards of the force, the concept of electric field".

Therefore, the electric field represents a space characteristic: to every point in space is associated a vector function with certain properties.

Some scientists talk about disturbance of the space, as if electric charges, ultimately generating the electric field, would remove perfection to the geometric space, introducing a sort of imperfection. Finally, this disturbance has not always being present: it propagates (for example in the vacuum space) with its own speed, precisely the propagation speed of electromagnetic waves in the vacuum. An analogy can be the following. In the calm air, before a gunshot, the atmosphere is in an equilibrium state. When a gun is shot there is a disturbance of the air and the noise is propagated with a certain speed. The same is true for the propagation of the electromagnetic field, being generated, for example from the "uncovering" of an electric charge that was "shielded" before.

c) wave-corpuscle dualism.

Unfortunately, the problems do not end here. The electromagnetic field (here again the use of this word with a different meaning!) highlights a feature that is characteristic of nature, but in the majority of cases cannot be visualised: the dualism wave-corpuscle. In fact, for electromagnetic radiation, sometimes we mean electromagnetic waves and some other times we mean photons. In the first case we highlight the wave aspect while in the other the corpuscular aspect. It can be demonstrated experimentally that if we make an action showing the wave nature of the beam (for example diffraction from a slit), we somehow destroy the corpuscular nature of the beam. Conversely, if we plan an activity that highlights the corpuscular nature of the beam (for example trying to count the number of photons that go through a device), we will destroy its wave aspect.

This is why, when using Maxwell equation to describe these phenomena, we use essentially a model, or an wave representation of the phenomena. Other theories are required to describe corpuscular phenomena.

III) CONCLUSION

This is the end of our first contribution. This was aimed at giving the basis to understand and discuss the interactions of electromagnetic fields with biological materials.

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In order to summarize basic physics issues, in particular the applications of physics to biology and medicine, the keywords used at the beginning can be used again. The concept of disturbance can help us to understand that if on one side measurements are essential to know a physics system, on the other side they alter the system that is being measured. The fact that terms like error and inaccuracy of measurements are used, should make us ponder on the fact that every type of experiment or measurement should be planned carefully, as well as on the fact that some inaccuracies cannot be eliminated. The reference to deterministic and probabilistic physics concepts allows us to focus on the fact that in the macroscopic world we live in, physics is essentially deterministic. However, if we want to understand well the interactions between electromagnetic fields and live matter, we have to use at least molecular biology means, and therefore remember that we enter the quantum physics field.

The concept of field in physics remains. It is a concept whose presentation suffers from equilibrium difficulties. It is presented either too simply, even superficially, or so abstrusely that it cannot be grasped. Maybe the best way is to think about a property given to each point in space. It remains to be understood that the electromagnetic field is not blocked in space or time, but is something that propagates in space instead.

We are now ready to face all the issues to better understand the several possible mechanism that explain the magnetic field interaction with biological matter, and its positive effects mainly on the human body.



Key words: Light scattering, penetration depth, laser-tissue interaction

Laser-tissue interaction principles: beam penetration in tissues (part II).

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ABSTRACT

In this communication, we continue in analyzing the principles of laser-tissue interaction, by considering a more advanced model in which light scattering is taken into consideration. Scattering is one of the fundamental phenomenon which is always present in the case of biomedical applications. After a brief introduction about the scattering of light and its physical modelling, we will consider how the presence of scattering modifies the laser penetration depth in tissues.

INTRODUCTION

Generally speaking, scattering of light occurs in media which contain fluctuations in the refractive index n, whether such fluctuations are discrete particles or more continuous variations in n. Referring to a light beam of wavelength λ and frequency ν , penetrating in a homogeneous medium, the definition of n is the following

n = c / v

where c is the speed of light in vacuum and v is the speed of light inside the medium. Experimentally we notice that light frequency does not change if the beam propagates into vacuum or into a different medium, but light speed does; it is always found that $v \le c$, so that $n \ge 1$. We can study scattering by considering a simple model in which scatterers are represented by particles whose characteristic dimensions are represented by R (Fig. 1). According to the value of the ratio R / λ , different results are found for the scattered light intensity distribution. On encountering one scattering particle within a homogeneous medium, photons travelling in a direction s are scattered into a new direction s'. The mean cosine g of the scattering angle θ , the angle between the incident s and scattered s' directions, is known as the anisotropy factor:

$$\mathbf{g} = \langle \cos\left(\theta\right) \rangle \tag{1}$$

where <> indicates a mean operation. As the particle size increases, the intensity distribution increases in the forward direction. Therefore, the mean cosine tends towards a value of unity, the higher the g value the more forward-peaked the scattering.



Fig.1. Schematic representation of the scattering of a photon by a single particle encountered during penetration in a given medium.

LIGHT SCATTERING IN TISSUE

Scattering of light in tissue is caused by inhomogeneities such as cell membranes or intracellular structures. The scattering arises due to a relative refractive index mismatch at the boundaries between two such media or structures, e.g. between the extracellular fluid and the cell membrane.

In bulk tissue it is the average scattering (and absorption) properties that are important in describing light transport. The typical mean refractive index for tissue is in the range 1.39–1.41, an exception being adipose tissue at 1.46. Most tissues have a high g value in the range 0.7-0.97 which means the scatter is very forward-peaked. Cases with g=0 correspond to the so called isotropic scattering: all directions for the scattered photon have equal probability.

It is important then to consider the relevance of measurements of scatter from isolated cells or organelles to the scatter observed in bulk tissue. In tissue as a whole one must also take into account the intercellular order and structures present other than cells, such as collagen fibres. Moreover, in sufficiently thick samples of biological tissue, i.e. greater than $10-100 \mu m$ in most tissues, multiple scattering of light becomes significant.



Fig.2. Schematic representation of multiple scattering. The ballistic component refers to the undeviated intensity.

LASER PENETRATION: THE LAMBERT BEER LAW "REVISITED"

Let us consider a collimated laser beam impinging on a tissue surface (Fig. 3). Let us suppose to perform a series of experiments in which the same laser of intensity I_0 passes through the same tissue with increasing thickness (t).



Fig.3. Schematic representation of a laser beam of intensity I_0 impinging on a tissue (in green) of thickness t. The emerging intensity is represented by I. Scattering is neglected.

From previous communication, we know that the following relationship is valid in

the case of negligible scattering respect to absorption:

$$\mathbf{I} = \mathbf{I}_0 \exp\left(-\mu_a t\right) \tag{2}$$

Equation 2 is called the Lambert Beer law and represents the exponential decrease of the laser intensity with the tissue thickness (t); μ_a is defined as the "absorption coefficient", and depends on the laser wavelength λ and the specific tissue type.

In the case of non-negligible scattering respect to absorption, we can take into account multiple scattering events, so that we end by a simple and approximated formula:

$$I = I_0 \exp \left[-(\mu_a + \mu_s) t \right] = I_0 \exp \left(-\mu_{eff} t \right)$$
(3)
where
$$\mu_{eff} = \mu_a + \mu_s$$
(4)

is defined as the effective absorption coefficient which, being the sum of μ_a and μ_s , takes into account both absorption and scattering.

PENETRATION DEPTH

Out of equation 3 it is possible to define the laser effective penetration depth (L_{eff}) in the more general case in which both scattering and absorption are considered:

$$L_{\rm eff} = 1 / \mu_{\rm eff} = 1 / (\mu_{\rm a} + \mu_{\rm s})$$
 (5)

By combining Eq. (3) and (5) we obtain the following relationship:

$$\mathbf{I} = \mathbf{I}_0 \exp\left(-\mathbf{t} / \mathbf{L}_{\rm eff}\right) \tag{6}$$

The physical interpretation of L_{eff} is very similar to the one given to L (see previous communication): " L_{eff} is the depth (in the tissue) at which the laser beam intensity is reduced by a factor of about 3, in the case in which scattering is not negligible respect to absorption". This can be deduced by the substitution $t = L_{eff}$ in Eq. 6, so that we obtain: $I_{t=PD} = I_0 \exp(-1) = I_0 / e \sim I_0 / 3$ where PD = penetration depth.

It is very important to notice that this definition is again independent on the laser intensity $I_{\rm o}$ (and also independent on the laser power $P_{\rm o}$ impinging on the tissue surface): lasers of the same λ , in the same tissue, but with different power, will have the same effective penetration depth. The effective penetration depth

can be only changed by: (i) changing the laser wavelength or (ii) changing the tissue type. It is also important to compare the two cases of (i) negligible scattering (only absorption is considered) and (ii) nonnegligible scattering (both absorption and scattering are considered in the model). In both cases it is possible to define a global behaviour of the laser intensity, which follows an exponential decay inside the tissue and which can be characterized by a penetration depth (case (i)) and effective penetration depth (case (ii)) respectively. In general, if we consider a given tissue and a given laser and apply both models represented by Eq. 2 and 3, we will notice important differences. As μ_{eff} is greater than μ_a (see equation 4) we will find a different penetration, given by L and L_{aff} respctively, with $L_{eff} < L$.

This is only a part of the story. As, in fact, scattering is characterized by a change in propagation direction (see Figs 1 and 2), it will also contribute in enlarging the beam dimensions while the beam penetrates in the tissue. As a consequence, the beam mean intensity will decrease, as the laser power is fixed but the beam area has enlarged. Models of beam enlargement are beyond the scope of this communication. Nevertheless this is a non-negligible "side effect" due to the presence of scattering. In order to illustrate the above described concepts, let us consider one example: a given laser (λ and laser power at the interface are fixed) impinges on different tissues, characterized by the same absorption coefficient (μ_{a} is fixed) but different scattering properties (μ_{e} is not fixed). In a first case we model the interaction by considering μ_a only, in the



Fig.4. Laser penetration in different tissue types, characterized by an increasing value of μ_{*} , starting from $\mu_{*}=$ 0. Tissue – air interface is at coordinate zero. In all cases: $\mu_{a}=$ 5/cm and laser power impinging on the tissue is 5W.

other cases we consider both μ_a and μ_s . From the graph represented in Figure 5 it is possible to notice that $L_{eff} < L$ and that L_{eff} decreases as μ_c increases.

The four cases represented in Fig. 4 reflect four different tissue types of increasing scattering coefficient μ_a . Laser power at the interface air – tissue is held fixed. In these cases we have a different penetration depth. As a consequence of the hypothesis of non-negligible scattering, the laser beam dimensions do change while penetrating into the tissue, even if this does not appear explicitly in the mathematical expression for I or L_{eff}.

CONCLUSIONS

Light scattering occurs in all tissues, its magnitude depending on specific tissue type and laser wavelength. Tissue most important scatterers in the visible – NIR range are cells and protein structures (e.g. collagen fibers).

Simple models of laser-tissue interaction include only light absorption processes. If we better model the interaction between a given laser beam and a given tissue by introducing the scattering, we obtain an inferior penetration depth respect to the case in which only absorption is present. It is important to remember that the comparison is made with the same laser wavelength and the same tissue type; this means that we compare two models between them, applied on the same physical problem. In general, in fact, the penetration depth depends on λ , μ_{a} and μ_{e} so that if we compare different lasers and / or different tissue type, we have to calculate the effective penetration depth (L_{aff}) case by case before making a comparison. While changing the penetration depth, scattering affects beam section area, which increases, thus decreasing the beam mean intensity.

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Key words: Laser-tissue interaction, thermal effects, PIF formula, Hiltherapy.

Thermal effects of NIR laser radiation in biological tissue: a brief survey.

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ABSTRACT

In this survey the laser-tissue interaction has been considered, with particular attention to thermal effects. Then Pulse Intensity Fluence formula for the hiltherapy pulse was retrieved. Thereafter PIF formula was applied with the lasers parameters used in some medical laser application to compare PIF values. In our opinion, PIF formula is easier to better understand HILT features and its differences with LLLT and Continuous Wave (CW) Power Lasers

Laser tissue-interaction has two main purposes: diagnosis and therapy. While no permanent change in tissue occurs in the diagnostic field, the ultimate objective of the therapeutic use of laser is to cause some sort of a modulated tissue damage that would be beneficial for the patient. The variety of interaction mechanisms that may occur when applying laser light to biological tissue is manifold. Specific tissue characteristics as well as laser parameters contribute to this diversity. Most important, among optical tissue properties, are the coefficients of reflection, absorption and scattering. Together, they determine the total transmission of the tissue at a certain wavelength. In addition, the following laser radiation parameters are equally important: wavelength, exposure time, applied energy, focal spot size, energy density and power density. Among these, the exposure time is a very crucial parameter when selecting a certain type of interaction.

Usually, laser-skin interaction can be categorized into five aspects [1], namely:

1. Photochemical interaction: this takes place at very low power densities (0.01 - 50 W/cm²) and long exposure time ranging from seconds to continuous wave.

2. Thermal interaction: the radiation is absorbed by the tissue and transformed in internal energy that produces a temperature increment. The irradiance could be continuous-wave or pulsed, typical power densities are from 10 to

 10^6 W/cm²; its temporal duration is from 1 μ s to 1 min.

3. Photoablation: UV radiation is used because the high energy of the photons can break molecular links and ionize atoms. By this way only focalized atoms and molecules can be affected. The exposition times are very short, from 10 to 100 ns, and irradiance is from 10^7 to 10^{10} W/cm².

4. Plasma-induced ablation: when power densities exceed 10¹¹ W/cm² in solids and fluids, a phenomenon called "optical breakdown" occurs with plasma formation and shock wave generation. In this process the typical pulse durations are from 100 fs to 500 ps.

5. Photodisruption: if breakdown occurs inside soft tissue or fluids, cavitation and jet formation may also take place. In this process a very short exposition from 100 fs to 100 ns and high-power laser, focused by a lens into the treated tissue, are used in this way, irradiances in the magnitude

of $10^{11} - 10^{16}$ W/cm² are obtained.

The majority of laser medical treatments, such as laser hyperthermia, coagulation, and surgery, involve thermal effects. To improve the treatment efficiency and for personal safety, accurate

analysis of thermal transport and thermal damage is of paramount importance. In general, predicting thermal tissue damage due to laser irradiation involves three steps:

1. Modeling the propagation and distribution of light within the tissue: when laser strikes a tissue, or passes from one type of tissue to another, it can be reflected, transmitted, absorbed, scattered, internally reflected or some combination of these phenomena. Various methods are used when dealing with propagation of light. Ray tracing is the simplest method, while solving Maxwell's equations of electromagnetic provides the most complete albeit almost impossible

analysis. One common technique is to consider the laser light in terms of photon paths, this method is called "photon transport"; its application to laser tissue interaction has been well validated [2]. A different approach relies on the Monte Carlo technique [3] to create a probabilistic model of light propagation in the tissue [4].

2. Estimating the temperature rise and distribution in the tissue: heat is generated in the tissue when photons are absorbed. In most cases of lasertissue interaction, а reasonable assumption is that convection, radiation, vaporization and metabolic heat effects are negligible. Heat transport is solely characterized by thermal tissue properties such as heat conductivity and heat capacity. If the rate of heat generation from the source term is known, the change in temperature can be calculated by using energy balance of the "bioheat equation" [1].

3. Predicting the thermal damage that would result: the thermal damage may be described mathematically by a rate process equation that defines a damage function [1; 5]. This damage function is expressed in terms of an Arrhenius integral.

Depending on the duration and peak value of the tissue temperature achieved, different effects like coagulation, vaporization, carbonization and melting may be distinguished. The spatial extent and degree of tissue damage primarily depend on magnitude, exposure time and placement of deposited heat inside the tissue. The absorption by water molecules plays a significant role in thermal interaction, and the absorption coefficient strongly depends on the wavelength of the incident laser radiation. Assuming a body temperature of 37°C, no measurable effects are observed for the next 5°C above this. The first mechanism by which the tissue is thermally affected can be attributed to conformational changes of molecules. These effects, accompanied by bond destruction and membrane alterations, are summarized in the single term "hyperthermia" ranging from approximately 42°-45°C. If such a hyperthermia lasts for several minutes, a significant percentage of the tissue will already undergo necrosis as described by Arrhenius' equation [1]. Beyond 50°C, a measurable reduction in enzyme activity is observed, resulting in a reduced energy transfer within the cell and immobility of the cell itself. Furthermore, certain repair mechanisms of the cell are disabled. At 60°C, denaturation of proteins and collagen occurs which leads to coagulation of tissue and necrosis of cells. At 100°C, the water molecules contained in most tissues start to vaporize. Due to the large increase in volume during this phase transition, gas bubbles are formed inducing mechanical ruptures and thermal decomposition of tissue fragments. Only if all water molecules have been vaporized, and laser exposure still continues, does the increase in temperature proceed. Above 150°C, carbonization takes place, which is observable by the blackening of adjacent tissue and the emission of smoke. Finally, beyond 300°C, melting can occur, depending on the target material.

However, not only the temperature achieved, but also the temporal duration of this temperature plays a significant role for the induction of irreversible damage. It is important to notice that many of the thermal effects described above can take place simultaneously in different areas of the irradiated volume, as a result of different temperatures locally developed because of laser radiation penetration in the tissue. When using laser pulse durations above microseconds, it is important to control the exposure time in relation to the tissue characteristic thermal relaxation time, in order to mitigate the effects of laser radiation in the target tissue volume. It should be taken into account that if the laser irradiation time is longer than the thermal relaxation time of the tissue, the heat can diffuse within the tissue beyond the typical optical penetration depth.

Many studies and models are presented in literature to study the thermal process in laser irradiated tissue; most of these studies are very specific and aimed at investigating thermal processes in certain organs and tissues of the body and under limited physical conditions, some are conducted to calculate temperatures profiles and thermal damage, while others develop models for calculating the tissue thermal response to laser irradiation [6-29].

In their work D. Fortuna and L. Masotti [30] synthesize in one formula, the "pulse intensity fluence" (PIF) formula, the Hiltherapy pulse features. Correlating their clinical and experimental data with the biological effects of Hiltherapy they defined the Hiltherapy domains and indicated a range of acceptable PIF values for tissue regeneration: from just under $0.2 [J/cm^3]^2$ to just under $1.0 [J/cm^3]^2$. Below 0.1 $[J/cm^3]^2$, there may be just an anti-inflammatory effect and not a regenerative effect; whereas for PIF values exceeding 1.0 [J/cm³]² there may be a histo-toxic effect.

In this paper we applied the PIF formula to the laser configurations used in different applications to evaluate the relationship between the biological effects with the PIF values. The formula is:

$$PIF [J / cm^{3}]^{2} = I_{p} \tau_{on} \frac{E_{p}}{10,07r_{sp}^{3}} \alpha \frac{\tau_{off}}{\tau_{on} + \tau_{off}}$$

were I_p is the peak intensity (W_p/cm^2) that is the peak power (W_p) divided by the surface area of the spot (cm^2); τ_{off}

is the pulse duration; E_p is the energy per pulse; r_{sp} is the spot size ray; α is the water absorption coefficient that varies in relation to λ ; and τ_{off} is the turned off phase.

It should be noticed that, if the radiation is a continue wave, τ_{off} is almost zero so that the PIF value is well below the acceptable PIF values for tissue regeneration, therefore only the pulsed laser radiation can be considered.

Opposite to surgery lasers, which have high power and are capable of tissue destruction, those used in physical medicine and rehabilitation have low power (1-20 mW) and have no thermal effect. They are capable of cell photobiostimulation and healing. This photobiostimulation effect is believed to promote tissue healing and repair while the bioinhibitory effect promotes pain management and relief. The clinical effects of laser light include marked improvements in wound healing, nerve repair, musculoskeletal pain and various inflammatory processes. However, one of the most confusing aspects of light therapy is explicated by dozens of published reports, which fail to find any effect from low laser therapy.

Regarding the safe use of lasers, there are several documents and guidelines dealing with the damage they can cause mainly to eyes (organs at higher risk) and secondarily to the skin. The ICNIRP (International Commission on Non-Ionizing Radiation Protection) published the guidelines on limits of exposure to laser radiation of wavelengths between 180 nm and 1400 nm to establish the basic principles of protection against optical radiation emitted by lasers and that are considered to be adequate for the general population as well as for occupational exposure [31-33].

The limits presented in these guidelines were considered in the European normative in the directive 2006/25/EC [34] as: "Adherence to the exposure limit values should provide a high level of protection as regards to the health effects that may result from exposure to optical radiation."

The same directive was implemented in the italian legislature with the D.Igs 81/2008 [35]. If we consider the limits for the skin, for a wavelength of 1064 nm, an exposure time of 150 µs and a spot size of 3.5 mm, the energy density limits is 0.6 J/cm². Applying these values for wavelength, spot size and exposure time in the PIF formula we obtain a PIF value of 0.06 [J/cm³]², just below the lower limit for the Hiltherapy. We have to consider that the safety limits are much lower than the pain thresholds as adopted by the standard DIN 33403 [33; 36].

To understand the characteristic of the pulse in the Hiltherapy we can apply the PIF formula to the characteristic variables of some laser applications in medicine. Many papers found in literature are missing an important factor for the formula therefore, the PIF values cannot be achieved. Those works where all terms of the PIF formula are present, can be divided considering the exposure time: ultrashort pulse, from fs to ns, are used for tissue ablation, for treatment of cutaneous lesions with a selective photothermolysis or for very particular applications such as the DNA transfection; short pulse, from few µs to few hundred µs, can be used in Hiltherapy but also in both ablative and nonablative treatments; from ms to s pulse, papers can be found about temperature and thermal effects in different tissue, laser welding of connective tissue, laser biostimulation, permanent damage of blood vessel and collagen synthesis. In the following we report some of these works calculating for each one the PIF values.

For instance, the work of M. Leandri et al. [37], studied skin temperature during and immediately after irradiation with pulses by Nd:YAP laser. They found that Nd:YAP pulses yielded temperatures that were correlated with pulse energy, but not with pulse duration; much higher temperatures were obtained irradiating blackened skin than white skin (ranges 100-194°C vs 35-46°C). Temperature decay was extremely slow in white skin, reaching its basal value in more than 30s. Pulse duration was 12 ms with a spot of 6 mm diameter. Energy was increased from a minimum of 0.5 (energy density 18 mJ/mm²) to a maximum of 4.5 J (energy density 159 mJ/mm²). Considering the absorption coefficient at the Nd:YAP wavelength (1340 nm), the following PIF values were obtained: PIF = 650 $[J/cm^3]^2$ for the maximum energy of 4.5 J;

PIF = 72 $[J/cm^3]^2$ at energy 1.5 J; PIF = 30 $[J/cm^3]^2$ at 1 J and

 $PIF = 8 [J/cm^3]^2 at 0.5 J.$

With the lower pulse the temperature increases of about 3°C without warm perception. A. da Costa Ribeiro et al. [38] investigated the thermal effects and the morphological changes after diode laser irradiation (810 nm) of root canals. Samples were irradiated in pulsed mode, with a duty cycle of 50% at 1.25 W (mean power), 10 Hz, \emptyset = 400 μ m, 994 W/cm². The maximum temperature variations at the apical region were analyzed and ranged from 1.2° to 3.3°C (group 3). From these parameters PIF = $146 [J/cm^3]^2$ despite this, thermal damage is absent, but it must be remembered that in this case the laser interacts directly with dentine and the mechanism of heat conversion depends directly on the tissue constituents and the irradiation wavelength. The dentin absorption coefficient is low for the wavelength used in this work ($808 \pm 5 \text{ nm}$), so scattering is predominant against absorption [1].

In a report of a study on the application of laser-activated nanoparticles in the direct welding of connective tissues F. Ratto et al. [39] achieved the local denaturation of the endogenous collagen filaments, which reveals that the treated area reached temperatures above 50°C, with an 810 nm diode laser pulses of 40 msec and approximately 100–140 J/cm² emitted by a 300- μ m core fiber. Also for these parameter the PIF value is high 4 ÷ 8 · 10³[J/cm³]².

The laser biostimulation applied by P. Vescovi et al. [40] that used Nd:YAG laser (power 1.25 W, frequency 15 Hz, fiber 320 umin diameter) defocalised at 1-2 mm from the tissue (theoretical PD 1555 W/cm², theoretical Fluence/ min 167.94 J/cm²) leads, assuming a 2 mm size spot, to a PIF = 7.4 $[J/cm^3]^2$. In a study of J. K. Barton et al. [41], the probability of permanent damage to a given type and size of blood vessel was determined as a function of fluence at the top (superficial edge) of the vessel lumen. A 532 nm wavelength, 10 ms pulse duration, 3 mm spot size and radiant exposure 2-20 J/cm2 laser was used resulting in PIF values from 0.003 to 0.31 [J/cm³]². Visible clearance (indicating permanent blood vessel damage) has been obtained at radiant exposures of 9.5-12 J/cm².

Nonablative methods may produce collagen synthesis in sun-damaged skin. V. G. Prieto et al. [42] studied sundamaged skin treated with a 1064 nm Nd:YAG laser (130 J/cm², triple pulse, 7.0/7.0/7.0-millisecond pulse duration, 75 - millisecond delay, 6 mm spot size and application of a thin coat of waterbased cooling gel). The end point of therapy was mild erythema, but in the settings employed, there is no obvious morphologic damage to the epithelial and mesenchymal structures in the skin. Their data indicate that treatment with Nd:YAG may result in increased collagen deposition in the papillary and upper reticular dermis. The PIF in this configuration is $[J/cm^3]$.

In an optical-thermal-damage model

of the skin under laser irradiation, developed by using finite-element modeling software by B. Chen et al. [43; 44], the predictions are compared to experimental measurements for a 2000-nm laser irradiation. The model enables the authors to verify the suitability of the American National Standards Institute (ANSI) maximum permissible exposure (MPE) standard for a wavelength of 2100 nm with exposure duration from 0.1 to 1 s and 3.5-mm beam diameter. The total exposure energy at the ED50 damage threshold is reported for three beam diameters (4.83 mm, 9.65 mm and 14.65 mm) and four exposure durations (0.25 s, 0.5 s, 1s and 2.5s).

Replacing the values in the PIF formula for the two smaller exposure duration we obtain the following values:

- $\tau_{on} = 0.25 \text{ s}$, $\emptyset = 0.48 \text{ cm}$ $E_{th} = 0.66 \text{ J}$ PIF = 360 [J/cm³]².
- $\tau_{on} = 0.5 \text{ s}$, $\emptyset = 0.48 \text{ cm}$ $E_{th} = 0.75 \text{ J}$ PIF = 300 [J/cm³]².
- $\tau_{on} = 0.25$ s, $\emptyset = 0.965$ cm $E_{th} = 2.12$ J PIF = 120 [J/cm³]².
- $\label{eq:tilde} \begin{array}{l} \bullet \ \tau_{\rm on} = 0.5 \ \text{s}, \ \ensuremath{\mbox{\varnothing}} = 0.965 \ \text{cm} \\ E_{\rm th} = 2.47 \ \text{J} \ \ \text{PIF} = 106 \ [J/\text{cm}^3]^2. \end{array}$
- $\tau_{on} = 0.25 \text{ s}$, $\emptyset = 1.465 \text{ cm}$ $E_{th} = 4.02 \text{ J}$ PIF = 51 [J/cm³]².
- $\tau_{on} = 0.5 \text{ s}$, $\emptyset = 1.465 \text{ cm}$ $E_{th} = 4.23 \text{ J}$ PIF = 38 [J/cm^3]^2 .

In the group of laser applications with a short pulse (from 1 to few hundred µs) there is the effect of laser radiation on meniscal tissue as examined by M. Bernard et al. [45]. They observed that laser systems caused greater damage to meniscal tissue and a more extensive healing reaction than cuts with mechanical instruments. Using the Nd:YAG parameters: 1.44 mm wavelength, 4.9 W power , 980 mJ energy per pulse, pulse duration 650 μ s, repetition rate 5 Hz and 800 μ m fiber, we obtain PIF = 9 • 10⁶ [J/cm³]².

K. Hayashi et al. [46] evaluated the effect of laser nonablative energy on the ultrastructure of joint capsular collagen. Laser energy was applied using a holmium: YAG laser and was delivered at 10 pulses/sec with a 250 usec pulse duration and a 400 µm fiber diameter. Transmission electron microscopy showed significant ultrastructural alterations in collagenous architecture for all laser treatment groups, with increased fibril cross-sectional diameter for each of the treated groups. For this reason we expected a PIF value greater than 1 [J/ $cm^3]^2$, indeed we obtained $[J/cm^3]^2$.

A. D. Izzo et al. [47] have pioneered a novel method of stimulating cochlear neurons, using pulsed infrared radiation, based on the hypothesis that optical radiation can provide more spatially selective stimulation of the cochlea than electric current. They found evidence that water absorption of optical radiation is a significant factor in optical stimulation. A diode laser was used for the optical stimulation with infrared radiation approximately between 1.92 and 1.94 µm and pulse durations were selected between 5 and 300 ms and the repetition rate of the laser was 2 Hz; the diameter of the fiber coupled was 200 µm. They estimate that the instantaneous temperature rise, associated with cochlear nerve stimulation after a laser pulse using a radiant exposure of 5 mJ/cm² ,would be 0.15°C at the distal tip of the optical fiber and 0.08°C at the neurons. The PIF value in this case is

 $0.08 \cdot \alpha | \lambda = 1,9$ amm = 9 $[J/cm^3]^2$

due to the high absorption of the water in the tissue at these light wavelengths.

The application of the ultrashort pulses is for example with the Q-switch Nd:YAG laser. The parameters for the treatment of cutaneous lesions (48) are 2 mm spot size and a high fluence of 12 J/cm² with pulse of the order 100 ns, so the PIF value is 2000 [J/cm³]². The high PIF value accounts for the fact that Q-switching works on the basis of selective photothermolysis.

Applying PIF formula for the ultrashort laser pulse ablation that removes material with low-energy fluence required and minimal collateral damage proposed by M.D. Feit et al. [49] we obtain a value of 18 [J/cm³]² due to 2 J/cm² 0.5 ps pulses with a repetition rate of 1 kHz and a laser spot diameter of 200 μ m, whereas PIF = 3·10³ [J/cm³]² to 25 J/cm² 5 ns.

A specific research was reported by S.-W. D Tsen et al. [50] where a very low power, near-infrared (1043nm) femtosecond laser technique was employed to enhance the transfection efficiencv of intradermallv and intratumorally administered DNA plasmid. They found that femtosecond laser treatment can significantly enhance the delivery of DNA into the skin and into established tumors in mice. In particular they found that mice receiving laser treatment with a laser that provides 500 fs duration pulses at 1043 nm wavelength with repetition rate 200 kHz, at a laser power density of 0.04 GW/cm², generated the highest transfection efficiency compared to mice treated at different laser power densities. This laser power density corresponds to a laser energy of 2.6 μ J/pulse with a spot size of 4 mm. The PIF value in this case is very small, approximately $6 \cdot 10^{-13} [J/cm^3]^2$.

In this work, consequences of thermal effects of laser radiation interaction with biological tissues have been considered. Moreover, the formula proposed by D. Fortuna and L. Masotti [30] to characterize the fluence intensity of the hiltherapy pulse was also considered. By inserting in the same formula the parameters used in other clinical applications of lasers, it is possible to obtain relative PIF values. These values do not ever fall in the range of effectiveness of hiltherapy. They are indeed either below the minimum threshold, as in the case of the limits for laser safety as contained in the ICNIRP guidelines and in the european and italian legislation (which is very conservative concerning workers), or beyond the maximum threshold because the laser radiation is used in this cases to cause selective damage to selected region of specific tissues.

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Chronic lumbago due to osteoarthritis treated by low level laser therapy.

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ABSTRACT

In cases of chronic Lumbago caused by osteoarthritis low level irradiation is a good alternative as physiotherapeutic treatment. PS we have observed clinically and objectively significantly efficacious results in 45 patients, men age 52; in a sample of 18 female and 12 male diagnosed with chronic lower back pain caused by osteoarthritis.

Eight treatment sessions were carried our, one session per week, with a Gallium Arsenide laser of 905 nm. The hand pieces of 16 diodes were used to irradiate 13 pints in the lumbo-sacral region for 60 seconds each.

The laser treatment was significantly effective in resolving pain in 33 of the 45 patients. Treatment permits combination with Paracetamol at low dosages.

INTRODUCTION

Chronic degenerative joint diseases and their symptoms, in a significant percentage of cases, can cause neurological complications, [1, 2], nervous system disorders and emotional imbalances [3], are often the cause of absence from work [4, 5]. Among the treatments against pain and inflammation which are characteristic of joint diseases [6], treatment with the low power Gallium Arsenide (GaAs) diode laser is offered as an alternative to regular medication. [7, 8, 9].

As with osteoarthritis of any joint, the clinical manifestation of lumbar osteoarthritis presents with pain and limitation of movement. Obesity, abnormal posture, joint overuse, traumatic compensations, instability of bone support structures, etc... negatively impact its development.

Seibert, Brockhausen and King [10, 11, 12], in their studies, reported that using pulsed laser light at a power of 10 mW, obtained pain relief.

Irradiating laser light on painful areas would act as mediator in the analgesia of the joint. As communicated tolerance of pain and sensitivity expressed by patients improves significantly after half a minute of irradiation at an energy o 2 mJ. [13, 14]. Double-blind and placebo control studies have indentified the analgesic effect of laser at low doses when irradiating during 30 seconds on trigger points, and referred pain in the wrist joint. According to Walker, effects of pain suppression mediated by the use of the laser would be a response of nerve endings to this particular kind of light. Nerve endings connected to the area of referred pain are photosensitive and capable of generating an action

potential in response to laser irradiation when appropriate doses and frequencies are used [15].

Low-power laser irradiation has been used to enhance the survival of surgical flaps and grafts, and to accelerate the process of wound healing, with no side effects being identified. The exact mechanism of cellular photo activation produced by the laser light is not yet entirely clear [16], however, numerous studies demonstrate in basic analyses in cell cultures and animal experiments, that there are grounds for clinical application, such as pain treatment [17].

Bjordal observed in animal studies that with doses of 6 to 10 joules (of energy density), significant anti-inflammatory effects are obtained [18]. In our study we have used doses of 0.4912 J/cm² on each of the treatment points of the lower back were pain was, and have also obtained good results. Although the dose is significantly lower as energy density, the SAEF (Total Energy Deposited per Treatment) are similar. In our study the SAEF and the energy density are identical and this leads us to believe that the therapeutic window of antialgic effect with the laser is related to the point of application and also the total energy deposited.

This study presents the use of the low power infrared laser (IR) in the treatment of lower back pain caused by osteoarthritis in 45 patients who received 8 treatment sessions. We objectively analyzed the evolution of pain and the improvement of general condition of patients, and also changes in the mobility of the lumbar spine.

MATERIALS AND METHODS The laser system

Treatment was performed with an infrared (IR) Gallium Arsenide (GaAs), pulsed laser diode 905nm wavelength (*Lux 16, Medilight, SL Espulgues de Llobregat, Barcelona*). This system has a console which houses the power source, the handpiece being pentagonal in shape and an

area of 10cm² housing the 16 diode laser, distributed equidistantly (Fig.1).



Fig.1. Points for the application of the laser, corresponding to the anatomical references of the lumbar and sacral-iliac area.

The peak power of pulsed emission from each of the diodes is 6 W. The total set of 16 laser diodes of the hand-piece that emit in unison is 96W peak power and 96mW. Mean power at a maximum pulse frequency of 5000 Hz and 200 ns laser pulse length. It is also possible to obtain a maximum average power of 314.572 nW, using the frequency of 16,384 Hz.

For treatment on each point, we selected the pulse frequency from among the various programs offered by device. Then, there are 15 possibilities of treatment in accordance with the pulse frequency used. In the present study, the pulse frequency used in each treatment was 4096 Hz per second, corresponding to program 13, which is equivalent to an average power of 4915 nW per diode, with total of 78.64 nW (16 diode laser).

During treatment, the aim was to cover the lumbar area, which was practically obtained by using a 10 cm2 hand-piece with programme 13. The total energy per pulse each diode for a minute's irradiation corresponded to 0.2949 Joules/diode and for all 16 laser diodes was 4.7184 Joules. The dose, that is to say, the energy density or fluence corresponding to each treatment (10 cm²) was 0.4718 J/cm².

Patients and treatment sessions

We treated 45 patients of both sexes, 27

Pt.	Sex	Age	Arthitis
1	F	40	1
2	Μ	42	2
3	F	42	3
4	F	42	2
5	Μ	42	1
6	F	43	3
7	Μ	50	2
8	F	50	2
9	F	50	4
10	Μ	50	4
11	7	50	2
12	Μ	51	3
13	F	51	2
14	Μ	51	1
15	F	51	2

Pt.	Sex	Age	Arthitis
16	F	51	2
17	F	51	2
18	Μ	51	3
19	F	51	2
20	Μ	51	4
21	F	51	1
22	Μ	52	2
23	F	52	1
24	Μ	52	3
25	F	52	2
26	F	52	2
27	F	52	2
28	Μ	53	4
29	Μ	53	2
30	F	53	3

Pt.	Sex	Age	Arthitis
31	F	53	2
32	м	53	1
33	F	57	2
34	F	57	2
35	F	58	3
36	м	58	2
37	м	58	4
38	F	58	3
39	F	59	1
40	м	59	2
41	F	59	3
42	F	60	2
43	Μ	60	1
44	F	60	3
45	м	60	2

 Table I. Control of the patients (sex, age and degree of osteoarthritis).

 F=Female; M=Male // Degree of osteoarthritis: 1) Very important, 2) Important, 3) Moderate 4) Early stage of osteoarthritis

female and 18 male, aged between 40 and 60 years (means age 52 years). All patients suffered from chronic lower back pain due to osteoarthritis (Table I).

In the selection criteria we took into account that the patients had x-rays confirmed diagnosis of osteoarthritis, with manifestations of chronic lower back pain for more than four annual periods of exacerbation. Patients had to have employment outside their homes, excluding those who were on sick leave or were unemployed due to physical disability, as well patients with over 10 kg excess weight. Neither, insulin dependent diabetic patients or those suffering from degenerative systemic diseases and/or obvious psychopathology were accepted. All patients underwent analysis of blood and urine. Interviews and basic tests for screening of infections and neoplasm were conducted, as well as to rule out metabolic disorders and inflammatory rheumatic diseases. Neurological examination was also conducted to exclude from the study patients receiving treatment for diseases of the nervous systems.

To study the possible correlation between the degree of osteoarthritis, its clinical expression and its relationship with the development and favourable or unfavourable changes experienced with treatment, the arthritis was scored as 1) Very Serious, when the patient was suffering constant pain, even at night turning in bed while sleeping; 2) Serious, when pain was preset during the day, but it was medium degree, allowing the patient to work, disappearing when at rest; 3) Moderate, when pain appeared only due to effort, and 4) Early Stage Osteoarthritis, when sometimes the patient experienced pain during overstraining which disappear with sleep.

With the aim of categorizing the symptoms suffered by patients and their characteristics, the Lattinen test was used, adapting it for this study. In the Table II, the intensity and frequency of pain and the degree of disability are shown. The patients informed as to the quality and hours of sleep and, likewise Paracetamol consumption through out to the study period was documented. (Table II).

Arthitis	Arthitis	
INTENSITY OF PAIN	LIGHT	1
	IRRITATING	2
	INTENSE	3
	VERY INTENSE	4
Frequency of the pain	OCCASIONALLY	1
	FREQUENT	2
	VERY FREQUENT	3
	CONSTANT	4
CONSUPTION	OCCASIONALLY	1
OF PARACETAMOL	REGULAR	2
(FREQUENCY)	MANY TIMES	3
PHYSICAL DISABILITY	LIGHT	1
	MODERATE	2
HOURS OF SLEEP	NORMAL	1
	WAKE SOME TIME	2
	WAKE SEVERAL TIME	3

Table II. Assessment parameters associated with pain.
 (Adapted from Lattinen test):

All patients, before starting the laser sessions, had sometimes taken anti-inflammatory medications; however, they were only admitted to the study after suspending medications for 15 days. Pain intensity was rated as 1) Slight, 2) Bearable, 3) Intense, 4) Very intense (Table II) according to criteria determined in an Analogue Rating Scale. Patients were recommended no to take medication for treatment of arthritis. cut could take Paracetamol 500 mg. up to maximum of 4 tablets per day if required. It was recommended to suspend any kind of physical treatment during the period of laser sessions. The patients were informed of the nature o the treatment sessions and agreed to respond to evaluations questionnaires.

All patients evaluated their degree of disability with the following classifications: **1)** Mild disability, and **2)** Moderate disability. No patient of the study used any form of aid to move or was totally disabled. (Table II)

Method of treatment

The treatment applied during the 8 sessions, one per week, was laser irradiation with the patient in prone position, radiating on the 13 selected points, 6 points distributed bilaterally and equidistant along the Paravertebral muscles: 3 points on the spinous processes of the lumbar vertebrae L3, L4, and L5 and finally 2 points in each of the sacroiliac joints. Irradiation time on each point was 60 seconds. The area of treatment applied to each point was approximately 20 x 20 cm. Which corresponds to the dimensions of the window of the hand piece which contains the 16 laser diodes, thus during treatment practically the whole lumbo-sacral area was irradiated.

When applying, the window of the hand piece rests firmly on the specified points without applying pressure, or causing pain, and always keeping a good contact with the patient's skin.

At the end of the first treatment session, patients were recommended relative rest, avoiding straining the lumbar region. As of the second treatment session, it walking on level terrain was recommended, in comfortable shoes, warming patients that they should avoid any painful manifestation; the emergence of pain would serve as a warning to cease the activity that they were doing. Regarding food, they could continue eating as usual, but patients who exceeded the corresponding average weight, were advised a balanced diet of 1000 calories.

Evaluation of results

The modified Lattinen test was completed in order to objectively assess the results of the evaluations that were conducted before starting treatment sessions, before the last sessions (eight month of treatment), and a month after finishing all treatment sessions. In these three cases, pain intensity and frequency of manifestation were assessed as were the intake of analgesics and the degree of physical disability caused by back pain and monitoring of sleep quality in all patients. To identify the intensity of pain and mobility of the lumbar spine, the patient had to make active movements without straining. The movements were lateralisation, rotation to either side, bending and stretching, within the range of lumbar articular motion of each patient.

The efficacy of laser treatments was described by each of the patients, the physiotherapists who carried out the treatment and physician not involved in the study. The evaluation was performed before the eighth session and month later. Efficacy was as: 1) Very Good, 2) Good, 3) Fair, 4) As before, 5) Worse.

1) Very good: when the discomfort and symptoms disappeared

2) Good: when the patient had occasional discomfort, but he could carry out his normal tasks.

3) Fair: when the patient had occasional discomfort and needed to take Paracetamol.

4) As before: when the patient experienced no improvement and continued taking his usual medication.

5) Worse: when the subjective and objective symptoms of the patient, determined in the adapted Lattinen test and questionnaires, showed a worsening of symptoms, compared with their evaluations before starting treatment sessions.

RESULTS

Only 3 patients did nor participate in the last treatment assessment but was interviewed by telephone, confirming that had undergone and improvement with regard to pain and the mobility of the lumbar spine. The remaining patients completed the treatment sessions and assessments. It was noted that 30 patients improved significantly with the laser treatment (Table III), although it was difficult for 6 of them to gain clear

	PATIENT		PHYSIOTHERAPIST		DOCTOR	
EFFECTIVEINESS	A	В	А	В	А	В
VERY GOOD	3	2	6	3	5	3
GOOD	31	28	34	31	33	31
REGULAR	8	12	2	8	4	8
EQUAL	3	3	3	3	3	3
WORSE	0	0	0	0	0	0

 Table III. Effectiveness of treatment according to patient, doctor and physiotherapist.

 A: Assessment of effectiveness before the 8th session of treatment

 B: Assessment of effectiveness of one month after treatment sessions.

criteria on the results, because during the treatment sessions they had ingested, for periods of one or two days, 50 to 100 mg. of Diclofenac TM per day, in additions to the Paracetamol allowed. Of the remaining 15 patients, 5 said they had had a poor response to laser treatment and preferred the NSAID (Nonsteroidal anti-inflammatory drug) a medication, they usually used before starting the laser sessions.

The Analoge Ratings Scale

In the analysis of pain showed significant improvement in 30 patients. The differences were most apparent during the course of treatment sessions, the intensity of pain significantly decreasing after the 3rd or 4th session (Table IV). Of the 30 patients who experienced a significant improvement, 27 were found to walk with greater ease, "not feeling the back" as they communicated. In the physical examination of the 27 patients, on whom it was possible to perform all tests and who responded to the questionnaires, it was noted that the range of lumbar joint mobilization had increased in all of them for both the rotation lateral bending, front bending and stretching; the improvement was greater in all these patients when comparing the values before starting treatment sessions with those of before the 8th session, that is, the last session.

Of all the patients of the study, 5 reported having experienced increased pain intensity after the first treatments, which disappeared after 24 to 48 hours. Three of these 5 patients required to take Paracetamol; however, the pain was not so severe as to prevent them continuing to work. Another 2 patients said they felt tired and held a sort of sedated feeling after each treatment session, especially after the first 2. All 30 patients who experienced an improvement with the laser sessions were able to perform their normal occupations (Table IV). 39 patients reported improved sleep quality (Table IV). Those who noticed pain when moving in bed while asleep stopped experiencing it. 23 patients commented they were in a better mood. (Table III, IV)

DISCUSSION

Currently, there is enough basic experimental material which claims most of the therapeutic effects observed at clinical level.

Most lasers used in medicine base their effects on phototermal reactions, originated when reaching a practically specific temperature that leads to changes in the tissue of a reversible or irreversible nature. However, there is another kind of effects that occur locally and systemically due to low-power laser irradiation, without a significant increase in temperature in the irradiated tissue as a result of the diffusion of photons in tissue.

Arthitis	Arthitis		ASSESSMENT 1ª *	ASSESSMENT 2ª *	ASSESSMENT 3ª *
	LIGHT	1	10	40	36
INTENSITY	IRRITATING	2	18	3	9
OF PAIN	INTENSE	3	12	2	0
	VERY INTENSE	4	5	0	0
	OCCASIONALLY	1	5	25	28
FREQUENCY	FREQUENT	2	18	9	9
OF THE PAIN	VERY FREQUENT	3	13	6	3
	CONSTANT	4	9	ASSESSMENT 2** 10 40 18 3 12 2 5 0 5 25 18 9 13 6 9 5 11 39 22 4 12 2 14 39 15 31 16 31 17 39 21 40 24 5 9 31 28 11 8 3 422 284	5
CONSUPTION	OCCASIONALLY	1	11	39	37
OF PARACETAMOL	REGULAR	2	22	4	2
(FREQUENCY)	MENY TIMES	3	12	10 40 18 3 12 2 5 0 5 25 18 9 13 6 9 5 11 39 22 4 12 2 21 40 24 5 9 31 28 11 8 3 422 284	6
PHYSICAL	LIGHT	1	21	40	40
DISABILITY	MODERATE	2	24	40 3 2 0 25 9 6 5 39 4 2 40 5 31 11 3 284	5
	NORMAL	0	9	31	31
HOURS OF SLEEP WAKE SEVERAL	WAKE SOME TIME	1	28	11	11
	WAKE SEVERAL TIME	2	8	3	3
TOTAL	INDICATIVE O (INDEX) VALUE		422	284	255

 Table IV. Results (Adapted from Lattinen test):

* Assessment 1th : Before the start of treatment sessions; Assessment 2nd: Before the 8th and final session; Assessment 3rd: One month after treatment sessions: This laser photo-activation translates into a "phtobiomodulating effects" that produce in turn anti-inflammatory and antialgic reaction. [19, 20, 21]

The analgesic effect of low power laser irradiation has been confirmed in studies reporting on photosensitivity in the irradiated areas, which would have consequences on the afferent conduction in thick diameter myelin fibres. It was observed that the speed of conduction increases during the laser irradiation. Under normal circumstances. the conduction of the thick sensory nerves have a slow conduction of the stimulus. These data suggest that laser irradiation with energies between 4 and 6 mJ, produce reactions in the forms of pain expression. Energies above those mentioned match the dosages of our study treatment. The studies showed that the analgesic reaction occurs when treatments are carried out with laser systems emitting in the infrared and this is due to the greater penetration into the skin of the infrared wavelength, and particularly that of 905 nm, with which the laser in our study operates. Infrared emission between 800-940nm corresponds to a window of deep absorption in the skin, which justifies the analgesic effect of the laser which would photoactivate never endings, with the result of pain relief [22]

Wu [23], indicates that pulse time between 50-150 ms would be best suited for the gradual decrease of the amplitude of the evoked response during laser treatment. Unlike the evoke that produce an electrical stimulus that remains unchanged, during laser treatment there is production of fatigue or habituation of the response of evoked potentials, even using small doses of laser energy.

The use of low power lasers for pain relief and inflammation caused by arthrosis is extensive [24, 25, 26, 27, 28]. Multiple studies find their effectiveness in medical indices, confirming such effectiveness in clinical practice.

The system of laser sessions used in our work corresponds to the frequency of sessions recommended for intensive treatment of pain [28, 29]. In the treatment of epicondylitis, according to Stergioulas [30] and Vasseljen [31], the effects of pain relief are not obtained until after some 3 treatment, which coincides with what the patients in our study expressed. In our case, the effects were evident after the 4th week after the start of treatment.

In the therapeutic use of low power lasers for pain, there is little agreement among authors with regard to wavelength, laser power and energy used. The pulse repetition frequency, duration and recurrence of treatments tend to vary both in the guidelines recommended by the manufacturers and the experience provided by the clinician. Therefore it is difficult to compare the results of our study with the response observed in the studies in the literature using other laser systems [32, 33, 34, 35].

The results obtained by the patients of our study in the clinical evolution, the subjective manifestations of pain and the objective detection provided by the questionnaires, present the low-power laser as being effective and so this could be solidly be considered an alternative therapy against joint pain. [36].

Faced with lower back pain, experienced by a significant part of the population, any efficient alternative treatment must be taken into account, such as the proposed laser treatment in our study. According to the perception of treatment by patients, we can describe the laser treatment as a convenient and welltolerated therapy. The laser treatment of pain is not an invasive method and its application is totally painless.

The results observed in the patients of our study suggest the possibility of combining laser treatments with painkillers and moderate exercise. Complementing laser treatment with exercises tailored to the possibilities of movement of the spinal column, taking into account the age and physical characteristics of the patient, are suitable in order to maintain, as far as possible, the elasticity of the vertebral joints [37]. Advantage could be taken of the synergy of beneficial effects by the laser and mild analgesics that would palliate the pain of joint disease which is sometimes difficult to alleviate [38, 39]. The positive effects experienced by patients, can be described as significant, since 30 of the 45 who could not move without analgesic and/or antiinflammatory medication, had managed to do so and experienced relief just with laser treatment sessions. 15 patients needed to take Paracetamol at some time during the study, without requiring other medications or time off work. This observation that the laser sessions in conjunction with Paracetamol intake can avoid a loss of work, suggests, as an alternative, the combinations of drugs and laser against chronic osteoarthritis. Paracetamol doses used for patients have a minimal yatrogenic effect and can be given for long periods.

The laser treatment was more effective in patients suffering from lower back pain of a shorter time of evolution. However, we believe that the individuality of the patient's character is a factor that has to be taken into account, as some patients are better disposed than others to improve. In our study we have taken into account the possible bias that might occur in the treatment of chronic pain in conjunction with the patient's psychosocial profile. Sometimes, chronic lumbar pain may be a manifestation of stress and/or may accompany situations of anxiety. In these cases, the pain needs prescription of myorelaxants and/ or psychotropic drugs, however, in our study, these drugs are not recommended, to avoid the possibility of masking the true effectiveness of laser treatment.

Men experienced better and clearer effects than women, however, the differences were difficult to assess due to the small number of patients, so this observations can no be taken as an absolute factor. During the study it was no possible to identify factors that influence the placebo response to laser therapy. Patients experienced improvement after the session, enjoying a better range of motion in joints and improving their quality of sleep. The approach of the study on a sample of patients for the most par not selfemployed professionals, could bias the results because it is well known that the personal interest of a patient whose funds are based on their own work has every interest in recovering as quickly as possible to return to their activities [40]. However, in the sample of 45 patients of our study, only 3 were self-employed and precisely one of them was the one who did not report better results after laser treatment. This observation supports the effectiveness of treatment performed.

CONCLUSIONS

This study suggests that low-power laser is effective in treating chronic lower back pain produce by osteoarthritis. The results of pain relief were significant, avoiding sick leave and taking painkillers and anti-inflammatory drugs in the case of most patients.

In the light of the results observed, we believe that the protocol used for the patients was effective in the treatment of chronic lower back pain, and that the laser sessions can be applied in combinations with Paracetamol pharmacotherapy.

DECLARATION

The authors claim to have no interest in the laser system used in this study, nor any commercial relationship with the manufacturer. This study is registered in the memory of clinical follow-up activities of the Foundation Antonio Gimbernat 2007-2008, Cambrils (Tarragona).

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CONCLUSIONS

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ACKNOWLEDGEMENTS

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

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