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The Regulatory Action of Fibro fog: Pain, Quality of Life, Sleep, Anxiety and Depression observed after 42 Months of Treatment: A Case Report

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Abstract

Fibromyalgia is a chronic syndrome that acts on the musculoskeletal system, causing disabling pain, in addition to many other symptoms. As one of the associated symptoms, there are cognitive changes, such as difficulty maintaining concentration and memory, known as Fibrofog. The difficulties imposed by cognitive dysfunctions can change the lives of patients with fibromyalgia, affecting family, professional life and social interaction. As a treatment for fibromyalgia, the combined use of laser and ultrasound has been of great value, reducing pain and improving quality of life. The present study followed a patient affected by fibromyalgia for 42 months after treatment with laser and ultrasound, quantifying questionnaires and scales: Visual Analogue Scale, Fibromyalgia Impact Questionnaire, Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale and Beck Depression Inventory – II. The results point to a reduction of over 90% for the improvement of the evaluated conditions of pain, quality of life, sleep, anxiety and depression, ending with the report of improvement in Fibrofog, where the patient, after treatment, started her graduation in physiotherapy. We conclude that the methodology employed, using the synergism of Laser and ultrasound, although it points to the improvement of Fibrofog in a case report, is widely used in the treatment of fibromyalgia for pain control, allowing new follow-ups to be carried out.

Keywords: Laser; Ultrasound; Sleep; Fibro fog; Anxiey; Depression

Introduction

Fibromyalgia is a painful, chronic and generalized syndrome of the musculoskeletal system, which causes disabling pain. In addition to the exacerbated painful aspect (hyperalgesia), other symptoms are associated, such as intense fatigue, non-restorative sleep, mood disorders (anxiety and depression), irritable bowel syndrome, paresthesia, edema sensation, headaches, morning anguish, paresthesia, cognitive issues, among others. Consequently, it generates disabilities and leads to psychosomatic and psychosocial changes [1,2].

As one of the associated symptoms, cognitive alterations are found, the difficulty in maintaining concentration and memory, defined as Fibrofog. Cognitive dysfunction can change the lives of patients with fibromyalgia, generating conditions that can be more painful than pain. There are reports of patients who report the condition of forgetfulness, declines in cognitive function, memory and mental agility [3-5]. However, although cognitive conditions that influence memory impair the performance of professional activities and can lead to disability, the so-called Fibrofog is not identified as a diagnostic factor [6-8]. Cognitive difficulties are reported in greater numbers (2.5 times) in patients affected by fibromyalgia compared to other patients with rheumatological conditions, reaching a variation greater than 76% to 82% approximately, of which 50% directly point to some type of discomfort or mental confusion as a symptom [6,7].

The treatment of fibromyalgia has two main aspects. The pharmacological and non-pharmacological aspects [8-10]. The pharmacological treatment component comprises a wide variety of medications, such as analgesics, anti-inflammatories, antidepressants, anxiolytics and anticonvulsants, all of which target pain and inflammation. The non-pharmacological treatment aspect is made up of 3 major areas of action: nutrition, which makes notes about food based on inflammatory foods and excess sodium; physical exercise, consisting of prepared activities based on workload, time and

frequency, capable of reducing fatigue and loss of muscle strength; and physiotherapy, consisting of a wide range of resources, whether manual or technological, that allow modulating pain. All this makes it possible to improve the quality of life [11-15]. However, due to the complexity imposed by fibromyalgia, there is no single intervention model, often requiring a multidisciplinary intervention [16].

In the last 5 years, as a physiotherapeutic methodological proposal grounded and technologically structured [17-21], the use of combined technologies of therapeutic laser and therapeutic ultrasound, applied to the palms of the hands, has benefited many people in the treatment of fibromyalgia, making it possible not only to control, but also totally eliminate the pain caused by the painful syndrome. This treatment, composed of technological and methodological innovation, has equipment that allows the synergistic use of Laser and Ultrasound (developed by the Institute of Physics of São Carlos, University of São Paulo and produced by the company MMOptics, Brazil), performing the superimposition of the fields and that, in this way, potentiate the effect. In this context, both technological physiotherapeutic resources have analgesic and anti-inflammatory action, and, in the case of ultrasound, they are also capable of promoting the reduction of muscle pain, through their thermal action, providing a condition of vasodilation and increased signaling speed, due to a greater ionic

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permeability in tissue membranes [22] and in the case of Laser, through the photobiomodulation process, an enzymatic modulation occurs, promoting greater ATP production, which allows a positive performance in organisms, mainly in a state of depression or illness [23,24]. As a methodological innovation, the application approach in the palms of the hands, shows to be of systemic homeostatic function [19,20], where the nervous conduction of the stimuli, allows the reduction of the intracranial pressure directly and positively affecting the pain center next to the prefrontal cortex, normalizing the hypersensitivity of the condition imposed by fibromyalgia. As published by Aquino Jr et. al (2022) [22], the systemic action extends to other regions through the parasympathetic systemic system (vagus nerve), producing bradycardic effects, reduction of stomach pain and irritable bowel control, among other related positive actions.

This systemic homeostatic action has also been identified as allowing the rehabilitation of patients affected by post-COVID-19 sequelae, the so-called long-term Covid, in matters involving pain, sleep, anxiety, depression, concentration and memory [25]. Such notes suggest that the treatment can be positive in the treatment of Fibrofog. Thus, the objective of this study was to accompany a patient affected by fibromyalgia and with clear symptoms of Fibrofog, for a period of 42 months after the intervention of 10 treatment sessions carried out with the synergistic technology of Laser and ultrasound, with the methodological approach application on the palms of the hands.

Materials and Methods

Approval and Location

The study was approved by the Ethics Committee in Research for Human Beings of Santa Casa de Misericórdia de São Carlos and by the National Committee of Ethics in Research, through CAAE 13789319.5.0000.8148, following resolution 466/2012, being carried out on the premises of Photodynamic Therapy Unit, the clinical research unit of the São Carlos Institute of Physics, University of São Paulo, São Carlos, São Paulo, Brazil.

Equipment and Patent

For the research, equipment capable of synergistic emission of therapeutic laser and therapeutic ultrasound was used, allowing the overlapping of the fields of action of the therapy at the same time. The equipment was developed by the Institute of Physics of São Carlos, University of São Paulo, and produced by the company MMOptics, patent number BR102014007397-3 A2, certified by the Brazilian Health Regulatory Agency (ANVISA) n° 80051420029, called RECUPERO^{*}.

Patient and Protocol

Female patient, white, 59 years old, diagnosed with fibromyalgia in 2006, but reports pain since 1989. Pain complaints include pain in lower limbs, upper limbs and trunk, with diffuse pain, in addition to fatigue, decreased muscle strength, poor sleeping conditions, headaches, stomach aches, irritable bowel, stress and depression. In addition, cognitive difficulties such as forgetfulness and difficulty concentrating are reported, notes correlated with the clinical picture of fibromyalgia and recommended as FibroFog [6]. The patient reported the use of several medications, such as antidepressants, anticonvulsants, antiepileptics, anxiolytics, anti-inflammatories and anxiety. There is no physical exercise by the patient.

The performed protocol made use of Laser and Ultrasound therapies synergistically and concomitantly. Estimates were made at 9 different moments: A) initial assessment, considered before treatment; B) evaluation after treatment; C) evaluation 6 months after the end of treatment; D) evaluation 12 months after the end of treatment; E) evaluation 18 months after the end of treatment; F) evaluation 24 months after the end of treatment; G) evaluation 30 months after the end of treatment; I) evaluation 36 months after the end of treatment; I) evaluation 42 months after the end of treatment. Late follow-up is established based on follow-up data from patients with fibromyalgia at 120 days and 300 days after the same intervention model established 20.

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Questionnaires and Scales

All assessments were performed at 9 different times: Before treatment, after treatment, 6 months after treatment, 12 months after treatment, 18 months after treatment, 24 months after treatment, 30 months after treatment and 36 months after treatment and 42 months after treatment.

Visual Analogue Scale

Pain assessment was performed using the Visual Analogue Scale (VAS), asking the patient to indicate the degree of her pain at the time of assessment. Data are displayed on a scale of 0 to 10, and the difference between moments was established as a percentage.

Fibromyalgia International Questionnaire

The International Fibromyalgia Questionnaire allows numerically quantifying the patient's quality of life, inferring questions of daily actions and establishing the degree of difficulty of these actions. The data are displayed in their entirety and the difference between the moments was established as a percentage.

PittsBurgh Sleep Quality Index

The Pittsburgh Sleep Quality Index (PSQI) is an evaluation instrument that allows, through a questionnaire, to assess the quality of sleep and its disturbances. The questionnaire allows a total score of up to 21 points, where the higher the value, the greater the disturbance and, therefore, the lower the quality of sleep. The data are presented in their entirety and the difference between the moments was established as a percentage [26].

Hospital Anxiety and Depression Scale (HADS)

The Hospital Anxiety and Depression Scale (HADS) has two subscales, for anxiety and depression, with seven items each. The global score in each subscale ranges from 0 to 21, where the higher the score, the greater the questions involving anxiety and depression with the patient. The data are presented in their entirety and the difference between the moments was established as a percentage [27].

Beck Depression Inventory - II (BDI -II)

The self-report scale, for surveying the intensity of depressive symptoms, called Beck Depression Inventory - II (BDI - II) is composed of 21 items, where the higher the score, the greater the symptoms of depression [28]. The data are displayed in their entirety and the difference between the moments was established as a percentage.

Statistical treatment

Comparisons between the conditions of Before treatment, after treatment, 6 months after treatment, 12 months after treatment, 18 months after treatment, 24 months after treatment, 30 months after treatment and 36 months after treatment and 42 months after treatment, were shown in percentage ratios due to this being a case study.

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Thus, the Visual Analog Scale, Fibromyalgia Impact Questionnaire, Pittsburgh Sleep Quality Index, Hospital Anxiety and Depression Scale (HADS) and Beck Depression Inventory – II (BDI – II) assessments are developed using the equation:

"Value % (Δ) = (Initial Value – Final Value) / Inicial Value × (100)".

Results

Figure 1 shows the follow-up of the treatment performed with laser and ultrasound technology, applied to the palms of the hands, during a period of 10 sessions. The figure illustrates the values of the visual analogue pain scale, at the moments before treatment, after treatment and every 6 months after treatment, up to a total of 42 months after treatment. It is possible to observe that before the treatment, the patient points to a pain level of 10 and after the treatment, the pain is completely reduced to level 0 (100% reduction). Also, the evaluations every 6 months after the intervention show that the level of pain presented continues with a value of 0, that is, still with a 100% reduction in the value observed before the treatment.

In (Figure 2), it is possible to observe the follow-up of the treatment performed with the combined laser and ultrasound technology, during the period of 10 sessions. The values of the Fibromyagia Impact Questionnaire are shown, which represents the quality of life, in the moments before the treatment, after the treatment and every 6 months afterwards until the 42 months after the treatment. It is important to consider that the higher the value observed, the lower the patient's quality of life, indicating a greater number of problems and limitations. In this way, it is shown that before treatment, a total value of 104 is quantified and after treatment, there is a reduction to a total value of 5 (95.2% reduction). When observing the values considered every 6 months after the intervention, we observed a reduction to a total value of 1, reducing to 99% in relation to the value observed before the treatment.

Figure 3 shows the follow-up of the synergistic laser and ultrasound

treatment, with 10 intervention sessions, in relation to sleep quality, according to the Pittsburgh Sleep Quality Index Score, in the moments before the treatment, after the treatment and in the follow-up performed at every 6 months after treatment (total of 42 months after treatment). It is considering that the higher the value observed, the lower the patient's sleep quality. The figure shows that before the treatment, the total value is 19, close to the maximum which is determined as 21, and after the treatment, the total value is reduced to 0 (100% reduction). Likewise, the value presented in subsequent evaluations, up to 42 months after the intervention, shows the maintenance of the reduction presented, with a total value of 0 (100% in relation to the value observed before the treatment).

Figure 4 illustrates the monitoring of the treatment carried out by the resources applied in a combined way of laser and ultrasound, in a period of 10 sessions, based on the evaluation of the Hospital Anxiety and Depression Scale (HADS) questionnaire, quantifying values for anxiety and depression. When observing the anxiety values, in the condition before the treatment, the total value was 21, and after the treatment, the total value was 21, and after the treatment, the total value was reduced to 1 (95.2% reduction). After 6 months, the reduction remained at 95.2%, a linear maintenance value up to 42 months of follow-up. Regarding depression values, in the pre-treatment condition, the total value was 20, and after treatment, a reduction of the total value to 1 (95% reduction) is shown. In the six-monthly periods observed, the reduction pointed to 100%, from 6 months after the intervention, to 42 months. It is considering that the higher the value observed, the greater the patient's anxiety and depression condition.

Figure 5 shows the follow-up of the synergistic laser and ultrasound treatment, through the evaluation of the Beck Depression Inventory - II (BDI - II) questionnaire, which assesses the condition of depression. When observing the values in the pre-treatment condition, the total value was 50. After the treatment, a reduction of the total value to 1 (98% reduction) is shown, a value that continues in the half-yearly follow-up until the end of the follow-up (98% reduction). reduction).



Figure 1: Follow-up of the treatment evolution during 42 months of a patient with fibromyalgia, according to the Visual Analog Scale (VAS). It is possible to observe 9 different times: before treatment, after treatment (after 10 intervention sessions) and every 6 months after the final treatment. The percentage difference before between treatment versus after treatment showed 100% and between before treatment versus the comparison performed every 6 months showed maintenance of the reduction at 100%.

> FOLLOW-UP OF TREATMENT EVOLUTION DURING 42 MONTHS FIBROMYALGIA IMPACT QUESTIONNAIRE 120 Scale 100 Fibromyalgia Impact Questionnaite 80 60 40 20 95.2% %66 %66 %66 %66 %000 %66 %66 0 Before Treatment Afte After 6 Months After 12 Months After 18 Months After 24 Months After 30 Months After 36 Months After 42 Months Treatme FIC 104

Figure 2: Follow-up of the treatment evolution during 42 months of a patient with fibromyalgia, according to the Fibromyalgia Impact Questionnaire (FIQ). It is possible to observe 9 different times: before treatment, after treatment (after 10 intervention sessions) and every 6 months after treatment until the final 42 months of follow-up. The percentage difference between before treatment versus after treatment showed 95.2% and between before treatment versus after 6 months showed a value of 99%. The same reduction continues in later values up to 42 months after intervention.



Figure 3: Follow-up of the treatment evolution during 42 months of a patient with fibromyalgia, according to the Pittsburgh Sleep Quality Index Global Score (Global PSQI Score). It is possible to observe 9 different times: before treatment, after treatment (after 10 intervention sessions) and follow-up every 6 months after 42 months of the final treatment. The percentage difference between before treatment versus after treatment showed 100%. When compared before treatment and every 6 months after treatment, kostram reduction values continued at 100% reduction, through the 42-month follow-up.



Figure 4: Follow-up of the treatment evolution during 42 months of a patient with fibromyalgia, according to the Hospital Anxiety and Depression Scale (HADS). It is possible to observe 9 different moments: before treatment, after treatment (after 10 intervention sessions) and after 42 months of final treatment, with follow-ups every 6 months. Regarding anxiety, the percentage difference between before treatment versus after treatment was 95.2%, a value that was maintained in all semester evaluations. Regarding depression, the percentage difference between before treatment versus after treatment was 95% and between before treatment versus 6 months after it showed a reduction to 100%, a value that was maintained in all evaluations, up to 42 months after the intervention.

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Figure 5: Follow-up of the treatment evolution during 42 months of a patient with fibromyalgia, according to the Beck Depression Inventory – II (BDI - II). It is possible to observe 9 different times: before treatment, after treatment and 6-month follow-up, up to 42 months after treatment. The percentage difference between before treatment versus after treatment showed 98%, a value that continues at each evaluation semester, until the end, at 42 months (98%).

It is considering that the higher the observed value, the greater the patient's depression condition.

Discussion

Fibromyalgia is considered a disabling disease, affecting approximately 6.6% of the general population, and an increasing prevalence among women, affecting 6.8% of women. This involvement is even more noticeable among the urban population, reaching 11.4%, while the rural population, slightly less than half of this value, reaching 5.2% [22,29]. The great limitation as a result of fibromyalgia, due to the number and diversity of symptoms presented, end up directly interfering with the patient's lifestyle, in their daily activities, whether in the family or professional context [30], impacting their personal, social and professional life, with constant reduction in quality of life [31,32].

Fibrofog, described by Donaldson et al, (1998) [33], as a union of 3 different cognitive disorders that had the patient affected by fibromyalgia, namely: a) decreased ability to concentrate; b) decrease in immediate write/short-term memory; and c) multitasking disability. Thus, his description simultaneously presents a feeling of mental confusion marked by a loss of clarity of thoughts, and accompanies the anguish complaining of memory loss [34].

Due to all the complexity that directly affects the quality of life of patients, the need to develop new methodologies and duly substantiated knowledge that allow the control of the fibromyalgia syndrome, restoring the quality of life of both the patient and the family, deeply affected over the years is extremely important.

In this context, a compendium of knowledge acquired in recent years [17-21,25], associated with the results present in this study, shows not only the path taken by the treatment, as well as a delicate structure of actions and reactions carried out by the synergistic treatment of therapeutic laser and therapeutic ultrasound, allowing systemic homeostasis of the syndrome.

The photobiomodulation process carried out by the action of the therapeutic laser, through the emission of red and infrared light, which are observed by cytochrome C oxidase, structures responsible for absorbing light present in the mitochondrial electron transport chain. This process generates several effects, far beyond the increase in ATP

production, allowing increased ionic permeation of Ca2+, Na+ and K ions, changing their concentrations in the intracellular environment, angiogenesis, in addition to stimulating anti-inflammatory, immunomodulatory, analgesic and tissue repair [35]. Therapeutic ultrasound, on the other hand, allows the transformation of electrical energy into oscillatory mechanical energy, allowing, due to its also thermal effect, to promote muscle relaxation, tissue secretion and reduction of inflammation, in addition to facilitating ionic permeation due to a cavitational effect along with to cell membranes [36].

The reduction in pain and improvement in the quality of life received by the use of therapeutic laser and therapeutic ultrasound, observed in figures 1 and 2, showing not only the immediate reduction, but the control of these symptoms over a period after treatment, are corroborated by previous studies carried out by our group [17-21]. Furthermore, we observe that, according to Aquino Jr et. al, (2022) [21], there is conduction of stimuli from photonic and ultrasonic resources through afferent pathways, once applied to the palms of the hands, reaching the brain, which results in a modulation of intracranial pressure, positively affecting the pain center in the prefrontal cortex, which throughout the treatment allows the hypersensitivity to pain, characteristic of fibromyalgia, to be effectively controlled. Likewise, as described in a broad study by Aquino Jr et al. (2021) [19], the application of these physiotherapeutic resources when applied correctly in the Thenar, Hypothenar and Aponeurosis regions, present in the palms of the hands, due to a vast amount of nerve endings and blood vessels, prove to be conducive to receiving the treatment, in reason for resulting alterations found by Albrect et. al (2013). However, contrary to that presented by the aforementioned study (Albrecht, 2013), the application in areas beyond the Hypothenar enhances the proposed treatment. By acting positively on the brain, the conduction of stimuli continues its therapeutic action through the parasympathetic pathway, where the vagus nerve influences processes such as bradycardia, reduction of stomach pain and irritable bowel syndrome [22], symptoms present in fibromyalgia syndrome.

In a 2022 study, using the same therapeutic approach in patients affected by Covid Longa, it was reported that, after a greater number of sessions, it was possible to restore concentration and memory, sequelae arising from the infection by Sars-Cov-2 [25]. By using the therapeutic model of fibromyalgia, the action obtained suggests as hypotheses the greater oxygenation due to the homeostasis of pO2 sensors affected by

the COVID-19 syndrome, as well as the greater neuronal reverberation, in an area adjacent to the prefrontal cortex that is responsible for by the formation of recent memory and, later, can be stored in a long-term memory 25.

The notes made in both studies, fibromyalgia [22] and Covid-19 sequelae [25], mention the importance of sleep quality, a fact linked to fibromyalgia studies [19-21], which point out that pain reduction allows for better sleep quality. Such notes corroborate our result observed in figure 3, where, through the Pittsburgh Sleep Quality Index score (Figure 3), the improvement in sleep quality is widely monitored over 42 months. Sleep in its different stages allows for greater action of neuronal reverberation, favoring improved concentration and memory [25].

All this action also, over time, results in a decrease in anxiety and depression, either by reducing the hyperalgesic condition, or by improving sleep or anxiety related to fibromyalgia and its different disabling symptoms, as observed in figures 4 and 5, respectively Hospital Anxiety an Depression Scale (HADs) and Beck Depression inventory - II (BDI-II), specific assessment tools for anxiety and depression [27,28]. The follow-up carried out over 42 months shows the constant evolution of the patient, favoring the use of synergistic laser therapy and therapeutic ultrasound. Cognitive evolution during this period provided the patient with the beginning of academic activities in the area of physiotherapy, following her new professional training.

Thus, the synergistic treatment of laser and therapeutic ultrasound allow, through a cascade of actions and reactions, the improvement of the fibromyalgia condition, which over time, act positively by reducing fibrofog, helping the patient's cognitive improvement.

Conclusion

The continuity of studies involving fibromyalgia and its symptoms is of great importance due to the constant increase in cases. Our study, although a case report, managed to follow up a patient for 4 months after the intervention model with laser and ultrasound, following the entire process over time. The reported Fibrofog was controlled, with rehabilitation of cognition, showing yet another positive result of the therapeutic model. This work strengthens the possibility and makes even more concrete the option of adopting the therapy model as a standard of non-pharmacological and non-invasive treatment.

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