

## The Combined Fotobiomodulation and Therapeutic Ultrasound: How does the Efficient Treatment of Fibromyalgia by the Palms Promote a Prolonged Effect?

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### Abstract

The Fibromyalgia is considered the second most common rheumatic disorder, with prevalence between 2% to 8% of the population, depending on the diagnostic criteria that are used. Symptoms are diverse and include a history of headaches, generalized pain, dysmenorrhea, chronic fatigue, irritable bowel syndrome and functional gastrointestinal disorders, among others. Thus, a state of centralized pain, where a lifelong disorder with early onset, can trigger pain experienced in different regions of the body and at different moments, being amplified divide to an alteration of the pain threshold. The photosonic treatment, which enables the combined action of physiotherapeutic resources, is based on the normalization of the pain threshold with the central nervous system. Were evaluated 51 patients who underwent photosonic treatment in periods after treatment of 120 days and 300 days, evaluating the Fibromyalgia Impact Questionnaire and the Visual Analogue Scale. Continuity of improvement was observed in relation to the Fibromyalgia Impact Questionnaire and the Visual Analogue Scale, in relation to the periods of 120 days and 300 days after treatment, significantly. The long-term efficacy observed in the present study shows the efficiency of photonic treatment and the recommendation of a periodicity tends to be beneficial for the maintenance of the physiological state obtained.

**Keywords:** Fibromyalgia; Fotobiomodulation; Therapeutic ultrasound; Photosonic treatment

### Introduction

Considered the second most common rheumatic disorder, fibromyalgia can have prevalence between 2% to 8% of the population, depending on the diagnostic criteria that are used [1]. The original diagnostic criteria for fibromyalgia, such as the counting of pain points, have their definition in 1.990, leading to a majority female population. However, the new criteria, based on symptoms without counting pain points, lead a fibromyalgia population with a woman: male ratio of 2:1 [2]. In this concept, the development of fibromyalgia can occur at any age, even in childhood, with an indistinct prevalence among different countries, ethnicities and economic conditions [1-3]. Symptoms include a history of headaches, dysmenorrhea, temporomandibular joint disorders, chronic fatigue, irritable bowel syndrome and functional gastrointestinal disorders, interstitial cystitis, painful bladder syndrome, endometriosis, as well as other symptoms such as back and neck pain [1,4].

Thus, we observe pain in different regions of the body, in a state of centralized pain, where a lifelong disorder with early onset, can trigger pain experienced in different regions of the body and at different moments. This centralization is aimed at the central nervous system or at the amplification of pain, and consequent alteration of the pain threshold [1,5]. In this way, treatment methods that understand centralized pain can obtain a better result.

Thus, the photosonic treatment developed by the Institute of Physics of São Carlos, University of São Paulo and by the Clínica MultFISIO Brasil [6,7] which enables the combined action of physiotherapeutic resources of photobiomodulation and therapeutic ultrasound generating the overlapping of therapeutic fields is based on the normalization of the pain threshold with the central nervous system [7]. The overlapping of the therapeutic fields allows

greater anti-inflammatory and analgesic action, potentiating the previously only singular effect. The results obtained are in the public domain [6-9], allowing the return of the patient's quality of life and the reduction of pain. Such therapeutic action is also seen in the treatment of osteoarthritis of the lower and upper limbs [10-13] and Temporomandibular Disorder [14].

The aim of this study was to evaluate patients who underwent photosonic treatment in periods after treatment of 120 days and 300 days, evaluating the Fibromyalgia Impact Questionnaire and the Visual Analogue Scale.

### Materials and Method

#### Approval and Location

The present study was approved by the Research Ethics Committee and the National Research Ethics Committee through CAAE 13789319.5.0000.8148, according to resolution 466/2012. To carry out the study, the dependencies of the Photodynamic Therapy Unit of Santa Casa de Misericórdia de Sao Carlos were used, under the coordination of the São Carlos Physics Institute, University of Sao Paulo, Sao Carlos, Sao Paulo, Brazil and at the MultFISIO Brasil Clinics in Sao Carlos, Sao

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Paulo, Brazil, a partner with the São Carlos physics Institute, University of São Paulo, São Carlos, São Paulo, Brazil.

### Patients and Protocol

This study was composed by 51 patients of different ethnicities, aged between 30 and 65 years, all female, all patients have a disease onset of more than 1 year, were divided into 2 groups. The first group with 40 patients (n=40) was reevaluated after 120 days of treatment. The second group of 11 patients (n=11) was reevaluated after 300 days of treatment. The photonic treatment was carried out twice a week (10 sessions - 5 weeks), using the following parameters: applications on the palms of hands ultrasound in 1 MHz, pulsed mode, frequency 100Hz, duty cycle 50%, SATA 0.5 W/cm<sup>2</sup>; Fotobiomodulation realized in wavelengths 660 nm, continuous mode, power 100mW and Irradiance of 60 W/cm<sup>2</sup>. The duration of each session was 6 minutes, with 3 minutes being divided in each palm. The evaluations were carried out at 3 different times; A) Initial, after treatment and 120 days after treatment; B) Initial, after treatment and 300 days after treatment. At all times, Fibromyalgia Impact Questionnaire and Visual Analogue Scale analyzes were performed.

### Equipment and Patent

This study used a prototype developed by the São Carlos Physics Institute (University of São Paulo), with the Technical Support Laboratory (LAT), patent number BR102014007397-3 A2. The current prototype was developed by MMOptics, São Carlos, São Paulo, Brazil. The equipment carries out the emission of Therapeutic Laser and Therapeutic Ultrasound in synergistic mode, promoting the formation of an “overlap of therapeutic fields”, enhancing analgesic and anti-inflammatory effects.

### Questionnaire and Scale

Patients were analyzed in three different times, considering initial (before treatment), after treatment (after 10 sessions of treatment) and relative time of evolution (120 or 300 days). During the temporal evolution, no type of intervention was realized. As control evaluation the Fibromyalgia Impact Questionnaire and the Visual Analogue

Scale were realized, consecutively to measure the improvement in the patient’s quality of life and level of ache of patients [6,7].

### Statistical Treatment

In this study, the statistical analysis was performed using InStat 3.0 software for Windows 7 (Graph Pad, San Diego, CA, USA, 1998). The data, in its totality, were expressed as mean and standard deviation. The level of significance was set at p<0.05. To analyze the normality of data, the Kolmogorov-Smirnov test was used. After wards, a one-way ANOVA with a post-hoc-Tukey-Kramer for comparison of temporal Evolution was used.

### Results

The present study makes a comparison of the temporal evolution of the photonic treatment at different times. Figure 1 shows the comparison of the temporal evolution when observing the Fibromyalgia Impact Questionnaire, in relation to the initial values, after treatment (5 weeks), after 60 days and after 120 days. The values presented in mean and standard deviation show the significant difference when compared initial versus after treatment (p<0.001), initial versus 60 days (p<0.001) and initial versus after 120 days (p <0.001). No significant difference was observed between after treatment versus after 60 days and after treatment and 120 days. It is also possible to observe the percentual values of reduction between the first comparison (56.5%), the second comparison (58.6%) and third comparison (60%), slightly variable in 120 days (3.5%).

When looking at Figure 2, it is possible to observe that the comparison of the temporal evolution, when the Visual Analogue Scale is analyzed, in relation to the initial values, after treatment, after 60 days and after 120 days. The values presented in mean and standard deviation show the significant difference when compared initial versus after treatment (p<0.001), initial versus after 60 days (p<0.001) and initial versus after 120 days (p<0.001). It was not possible to observe a significant difference between after treatment and after 120 days. The percentual reduction values between the first comparison (60%), the

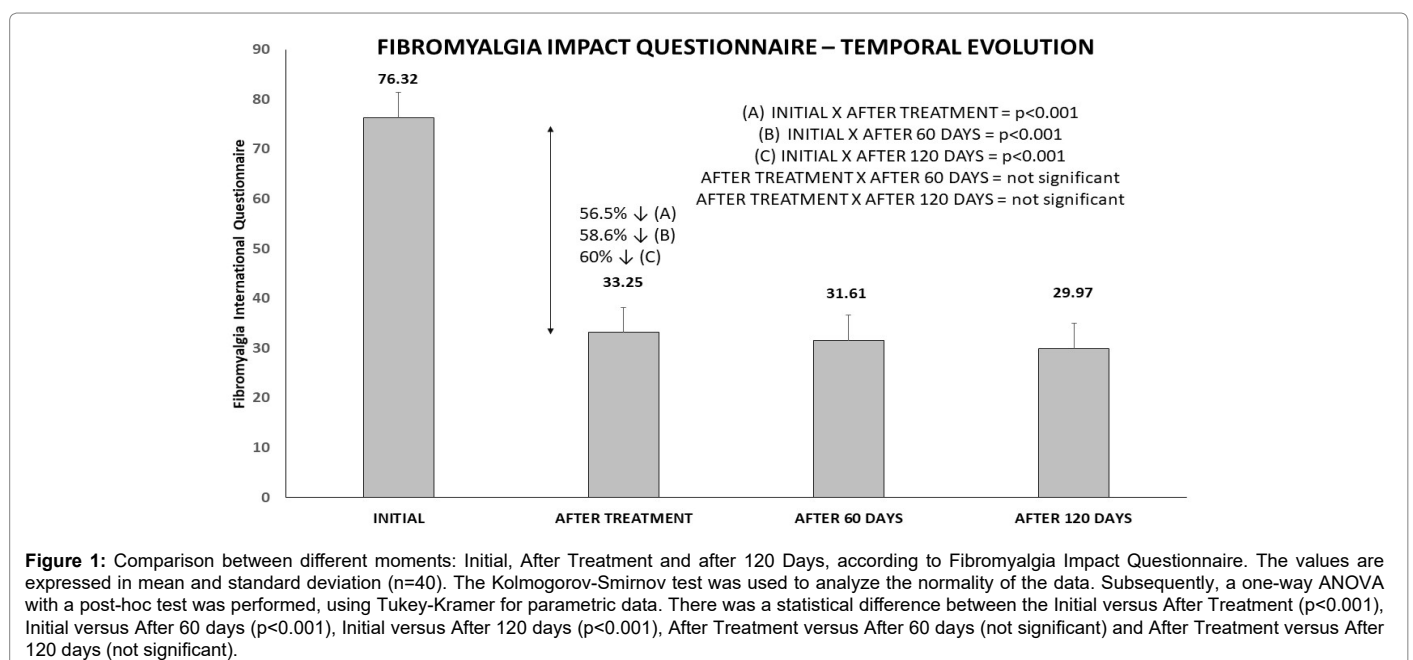


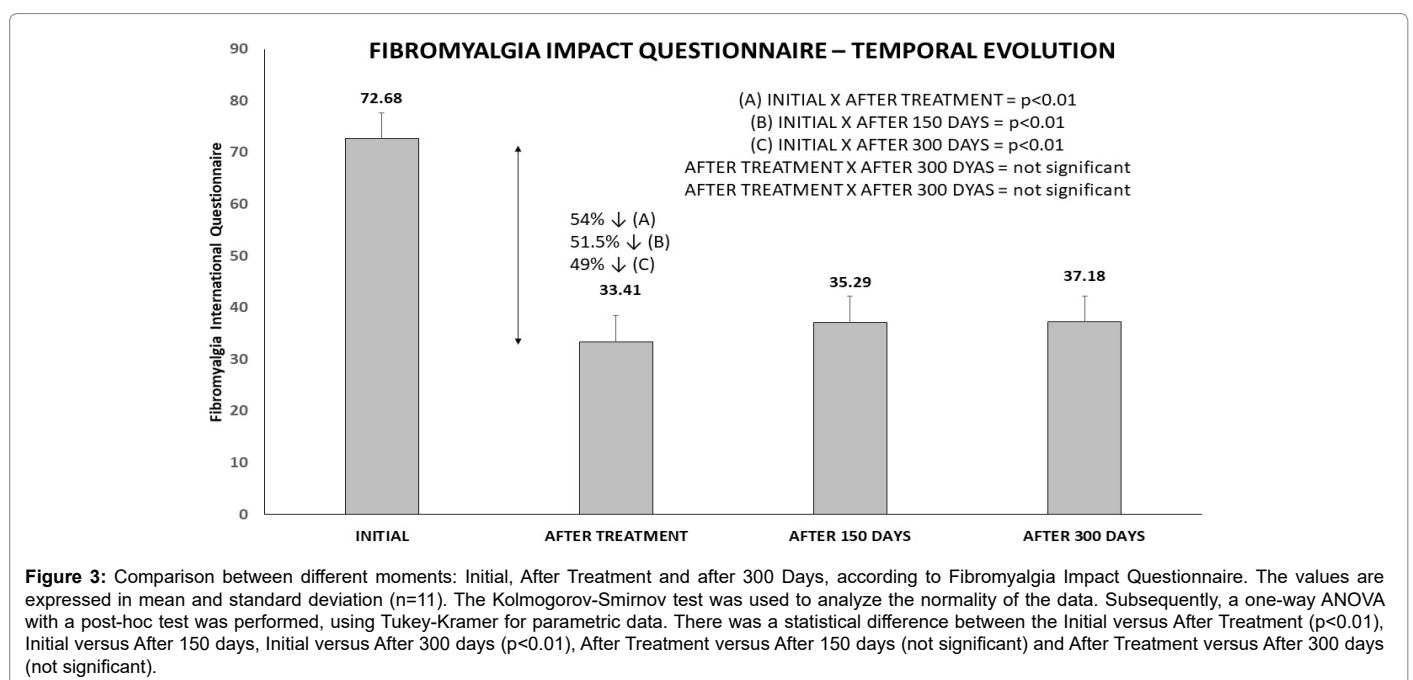
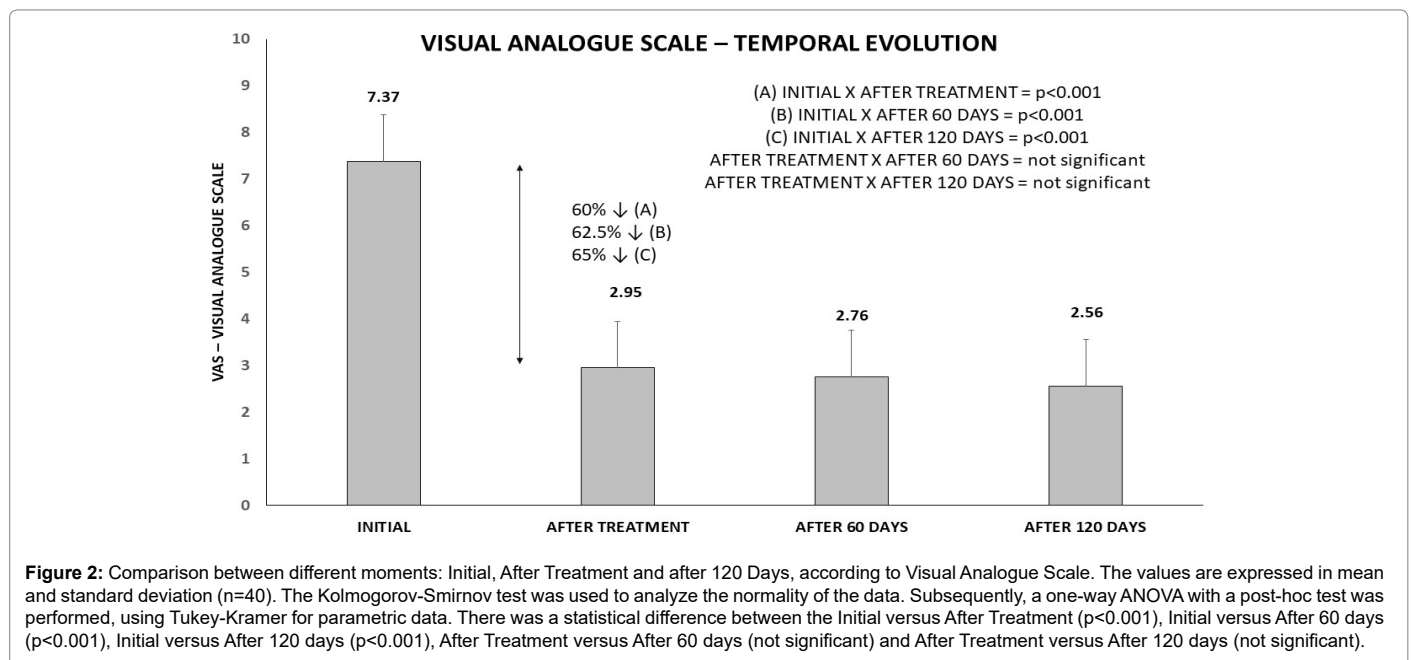
Figure 1: Comparison between different moments: Initial, After Treatment and after 120 Days, according to Fibromyalgia Impact Questionnaire. The values are expressed in mean and standard deviation (n=40). The Kolmogorov-Smirnov test was used to analyze the normality of the data. Subsequently, a one-way ANOVA with a post-hoc test was performed, using Tukey-Kramer for parametric data. There was a statistical difference between the Initial versus After Treatment (p<0.001), Initial versus After 60 days (p<0.001), Initial versus After 120 days (p<0.001), After Treatment versus After 60 days (not significant) and After Treatment versus After 120 days (not significant).

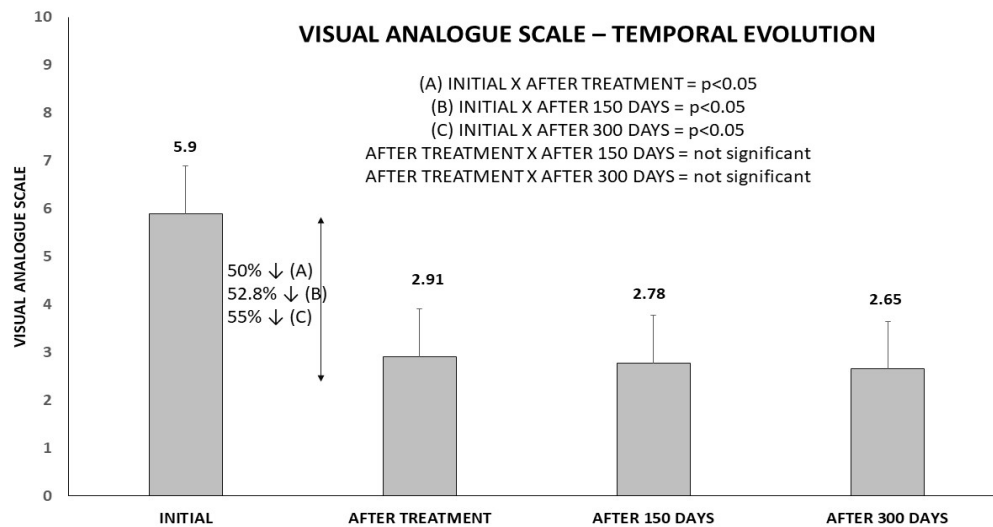
second comparison (62.5%) and the third comparison (65%) are also shown, with little variation in the time of 120 days (5%).

The figure 3 compares the time evolution according to the Fibromyalgia Impact Questionnaire over 300 days, in relation to the initial values, after treatment, after 150 days and after 300 days. The values presented in mean and standard deviation show the significant difference when compared initial versus after treatment ( $p < 0.01$ ), initial versus after 150 days ( $p < 0.01$ ) and initial versus after 300 days ( $p < 0.01$ ). No significant difference was observed between after treatment versus after 150 days and after treatment versus after 300 days. The percentual reduction values between the first comparison (54%), the second comparison (51.5%) and the

third comparison (49%) are also shown, with little variation in the time of 300 days (5%).

Figure 4, which show the evolution of the Visual Analogue Scale in 300 days, points out the relationship between the initial values, after treatment, after 150 days and after 300 days. Values are shown as mean and standard deviation, indicating the significant difference when compared initial versus after treatment ( $p < 0.05$ ), initial versus 150 days ( $p < 0.05$ ) and initial versus after 300 days ( $p < 0.05$ ). No significant difference was observed between after treatment versus after 150 days and after treatment versus 300 days. Percentage values of reduction between the first comparison (50%), the second comparison (52.8%) and third comparison (55%) are also shown, with little variation in the time of 300 days (5%).





**Figure 4:** Comparison between different moments: Initial, After Treatment and after 300 Days, according to Visual Analogue Scale. The values are expressed in mean and standard deviation ( $n=11$ ). The Kolmogorov-Smirnov test was used to analyze the normality of the data. Subsequently, a one-way ANOVA with a post-hoc test was performed, using Tukey-Kramer for parametric data. There was a statistical difference between the Initial versus After Treatment ( $p < 0.05$ ), Initial versus After 150 days ( $p < 0.05$ ), Initial versus After 300 days ( $p < 0.05$ ), After Treatment versus After 150 days (not significant) and After Treatment versus After 300 days (not significant).

## Discussion

Fibromyalgia is definitely known in relation to its severe inflammatory condition and disabling pain, generating a marked reduction in the patient's quality of life, negatively influencing not only professional life, but also personal life [15]. In this context, the need for a non-pharmacological and non-invasive treatment option is not only necessary, but essential for the treatment of this chronic syndrome. Thus, photosonic treatment, through its expressive results previously published [6-9], is increasingly based and established as a highly viable treatment for the treatment of fibromyalgia.

Understanding the condition of centralized pain, a situation related to changes or amplifications in the central nervous system, possibly modulating negatively the pain relief, allows the understanding of fibromyalgia and its responses, often failures in the action of opioids or operations to pain reduction [1,16].

Photosonic treatment, through the hypothesis described by Aquino 2021 [7], points out that the promotion of systemic homeostasis achieved happens through the application of conjugated therapy that allows the action of photobiomodulation and therapeutic ultrasound, applied in the palms of the hands. The palms of the hands, in the areas of hypothenar, thenar and palmar aponeurosis, are found in a vast number of nerve endings, which function as a receptor for the therapeutic resources used simultaneously [7]. As a result, normal peripheral and cerebral blood flow is restored [6], thus enabling the restoration of positive action, not only of excitatory neurotransmitters, but also of inflammatory cytokines in the cerebrospinal fluid [17,18], promoting the modulation of return to normal pain threshold, with the central nervous system. Systemic homeostasis then occurs in a positive way, generating homeostasis of metabolic abnormalities, reducing previously negative symptoms in fibromyalgia, improving sleep, gradually reducing fatigue, irritability, tiredness, in addition to normalizing the action of deep tissue nociceptors [19,20], allowing a thermoregulation condition.

Such ability to normalize pain, through all the factors generated above, leads us to the condition of long-term effectiveness, a condition

that, exposed to factors such as biological individuality, environmental, social and economic conditions, can promote variation in the obtained homeostasis picture, allowing the return to the abnormality picture before the homeostatic one. Also, through the observation of long-term effectiveness conditions observed in this study, for 120 days and 300 days, the normalization of the pain threshold shows no change after treatment, remaining similar to what was observed after the 10 sessions of photosonic treatment, proving to be extremely positive for the control of pain present in fibromyalgia and reversal of its negative systemic picture. In this context, our hypothesis of maintenance of pain threshold homeostasis occurs due to the continuity of normal blood flow, peripheral and cerebral, as well as the inflammatory picture of the disease, observed in previous studies [6,17,18]. However, due to the issues raised that can compromise the influence of the obtained homeostasis, periodic maintenance should be carried out, allowing, with greater safety, the maintenance of the homeostatic picture achieved by using therapeutic resources combined in this study and consequently providing a return on the quality of life to fibromyalgia.

## Conclusion

The long-term effectiveness observed in the present study shows photosonic treatment as a valuable non-invasive and non-pharmacological resource for the treatment and control of pain and the consequent return of systemic homeostasis in fibromyalgia patients. Issues such as biological individuality, as well as environmental, social and economic factors can negatively influence the obtained homeostasis. Thus, the recommendation of a periodicity in the photosonic treatment tends to be beneficial for the maintenance of the physiological state obtained.

## Ethical Approval

This study was approved by the Research Ethics Committee and the National Research Ethics Committee through CAAE 13789319.5.0000.8148.

## Conflicts of Interest

All authors confirm that there is no conflict of interest.

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