

## Phase angle as an assessment tool in the context of chronic musculoskeletal pain and ion cyclotron resonance treatments: A pilot observational study

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**Abstract:** The assessment of Chronic Musculoskeletal Pain (CMP) is fundamental for its management. An evaluation parameter that is gaining consensus in clinical practice is the Phase Angle (PA), obtained through bioelectrical monitoring with body Bioimpedance Analysis (BIA). To evaluate the reliability of the PA for CMP assessment, data from 53 patients (mean age 60 years) were observed. They had been evaluated through the Numeric Pain Rating Scale (NPRS) and the BIA, before (T0) and after (T1) a cycle of 10 treatment sessions with Ion Cyclotron Resonance (ICR). Following ICR applications, we detected a significant reduction in NPRS and a positive but not significant increase in PA values. Furthermore, given the misalignment in the significance of the positive trend of the two observed variables, it was not possible to define a clear correlation between pain and the bioelectrical values of patients. The study confirms the efficacy of ICR as a therapy for CMP. However, it was not possible to define a clear role of PA as a specific diagnostic tool for CMP. Although PA showed a promising trend, its non-significant correlation to the pain trend suggests investigating the topic in a more thorough and rigorous manner.

**Keywords:** Bioelectric impedance, Musculoskeletal pain, Magnetic field therapy, Rehabilitation.

### 1. Introduction

The term Chronic Musculoskeletal Pain (CMP) identifies a rather heterogeneous group of myofascial and joint problems that range from localized pathologies, such as Low Back Pain or Neck Pain, to more generalized pathologies such as Osteoarthritis and Fibromyalgia [1]. It is rather complex to determine the exact prevalence of CMP, due to the variability of the prevalence of individual problems converging within the pathology. However, it is estimated that a percentage ranging from 13.5 to 47% of the general population has experienced a pain that can be classified as CMP at least once in their life [2].

Howsoever, CMP can also be determined and perpetuated by a very wide range of factors. Although in most cases there is a mechanical cause attributable to injuries or physical overuse syndromes [2] CMP can also manifest itself following systemic and/or rheumatic pathologies. This is the case of fibromyalgia [3] and various forms of arthritis [4] which also involve persistent states of an inflammatory/oxidative nature and phenomena of dysregulation of the pain perception mechanisms [4].

Furthermore, CMP would appear to be strongly influenced by psycho-emotional [5] and nutritional factors [6] which can determine a predisposition to the genesis of the problem and at the same time become important elements perpetuating it.

Given the extremely complex nature of CMP, it is very important to identify all possible methods to assess and monitor the progress of the pathology, even beyond the predominant aspect of the presence of pain. In fact, although pain represents the dominant symptom of CMP, it seems clear that the causes of the problem can be extremely complex and linked to a series of organic, psychological and habitual factors, which deserve to be investigated and monitored with dedicated tools.

Among the least invasive and potentially most interesting evaluation methods in the clinical field, body Bioimpedance Analysis (BIA) is attracting growing interest in literature [7]. This method is based on the detection of the behavior of a low intensity current that is made to flow through the body of the patient [7]. The interpretation of the current flow allows to calculate two fundamental quantities such as Resistance (determined by the state of hydration of the body) and Reactance (due to the capacitance of cells membrane), relating them to each other in a single parameter defined as Phase Angle (PA), thus allowing to estimate the body composition of the patient and his state of hydration [7].

Although BIA is intended primarily as a method for evaluating body composition, several authors have used this instrument and the related PA parameter as a method for monitoring various clinical conditions [8] ranging from metabolic syndrome [9] to diabetic polyneuropathy [10] up to the boundaries of the field of musculoskeletal conditions [11-13].

The use of BIA as a monitoring tool in musculoskeletal pain has already proven useful in our previous research experience [14]. In that context, it was observed how the therapy consisting in the administration of Extremely Low-Frequency Electro-magnetic Fields (ELF-MFs), falling within the scope of magnetic field therapies and Quantum Medicine (QM) [14-18] was effective in improving musculoskeletal pain in the patients studied and, at the same time, in normalizing the values of Resistance and Reactance detected in the sample through BIA [14]. Magnetic field therapies, also applied in the form of Ion Cyclotron Resonance (ICR), are essentially based on the use of ELF-MFs, with frequencies typically in the order of a few Hz or kHz and intensities in the order of a few  $\mu\text{T}$  which, in pathological situations, positively interfere with the altered magnetic biofield of the human body [19] determining a balancing of the suffering physiological and metabolic patterns. These therapeutic effects of QM techniques, such as the ICR, seems to be mediated by its ability to counteract oxidative stress, reduce inflammation levels and increase cellular metabolism and the production of mitochondrial ATP [14-18].

based on our previous experience [14] we hypothesize that an even faster and more intuitive way to monitor the health status of patients suffering from musculoskeletal pain could be to use the single parameter of the PA, calculated according to the formula  $\{\arctangent(\text{Reactance/Resistance}) \times (180^\circ/\pi)\}$ , for a current typically of about 50 kHz that is made to flow through the human body [20]. This measurement method has proven to be the most reliable and repeatable in the bioelectrical evaluation of the human body [21]. This is particularly true in the field of the assessment of so-called "cellular health" although this application is still controversial and unclear in terms of mechanisms justifying its use [21]. Thus, more data and research are required on the reliability of BIA and, specifically, of the PA as tools for assessing health status in pathological contexts [21].

Therefore, in light of all these considerations, we decided to conduct an observation of previously collected data to determine the potential reliability of PA as a health status monitoring tool in a CMP context.

## 2. Material and Methods

This research is a pilot retrospective analytical observational study carried out at the Gemelli Molise Hospital (Campobasso, Italy) cooperating with Ce.Fi.R.R. institution (Center for Physiotherapy, Rehabilitation and Re-education) staff from January to June 2023.

All the procedures applied during the data collection comply with the safety regulations of the country where the study was made; the protocol is accessible to anyone who does not highlight specific contraindications during the initial clinical evaluation necessary for all patients who access the study facility. The protocol does not constitute experimental practice, as it applies the same standard treatment procedures used for all patients who do not present the above-mentioned contraindications. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained at enrolment from participants who were willing and able. Due to all these considerations and the lack of specific national laws stating the need for the submission of retrospective and/or non-pharmacological observational studies to an ethics committee [22, 23] the opinion of an ethics committee was not required. However, the Ce.Fi.R.R., as the main institution conducting the study, benefits from the ISO 9001:2015 accreditation for the implementation of observational clinical studies in the rehabilitation field (ACCREDIA Certificate no. IT15/0304): the accreditation certifies compliance with the highest standards relating to the procedures for conducting observational studies, in the absence of the evaluation by an ethics committee due to the national regulatory vacuum.

Data were observed from a total of 53 Caucasian patients (37 women and 16 men) affected by CMP, with a mean age of  $60.3 \pm 15.3$  years old, who underwent ICR treatment at the study site during the reference period.

All patients were diagnosed with CMP by medical doctors specialized in musculoskeletal disorders, following the criterion recognized in the literature that defines CMP as a persistent or recurrent pain condition deriving from musculoskeletal structures such as muscles, joints or bones that lasts for more than 3 months [1]. After the initial evaluation, patients received the medical prescription to perform a cycle of ICR treatments.

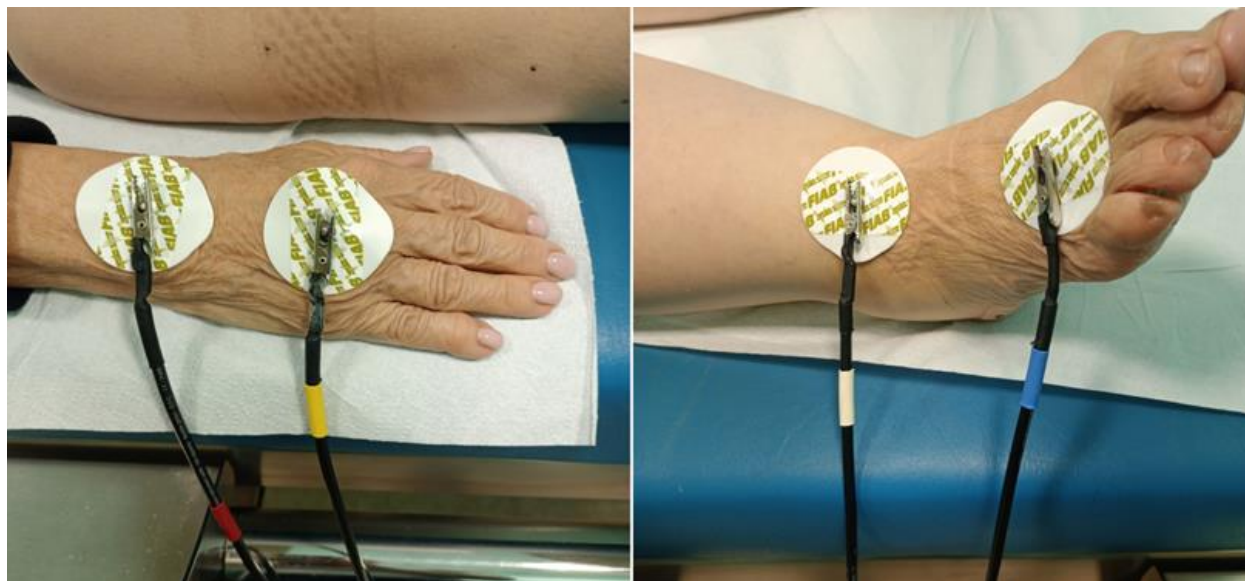
All patients presenting other pathologies in addition to the diagnosed CMP were excluded from the observation. In particular, all the patients presenting the following conditions were excluded: pregnancy, epilepsy, electrical implants, tumors, infections, tuberculosis, serious heart disease, neurological pathologies and an age under 18 years old.

All observed patients were evaluated before the beginning (T0) of the first ICR session and after the end (T1) of the last ICR session, through the following two assessment methods:

The Numeric Pain Rating Scale (NPRS): it is one of the most widespread instruments for measuring the pain perceived by patients. It derives from the Visual-Analogue Scale (VAS) and it is a unidimensional scale divided into ten levels, usually evenly distributed on a 10 cm long strip, with each number written on the strip corresponding to the level of pain perceived by the patient at the time of the evaluation. A score of 0 indicates the total absence of pain, while a reported value of 10 corresponds to the maximum level of pain imaginable and/or ever experienced by the patient [24]. This scale is reliable, easy to apply, and proved to be effective even in the presence of chronic dysfunctions of the musculoskeletal system [24]. In the case of the present study, patients were asked to express a value from 0 to 10 corresponding to the maximum level of pain perceived at their personal most insidious musculoskeletal level.

The BIA: as previously explained, this method is based on the detection of the behavior of a small current, typically at a fixed frequency of 50 kHz, which is made to flow through the body of the patient to then derive parameters such as Resistance, Reactance and PA [21]. This method allows to evaluate the body composition of the patient, in terms of lean mass and fat mass, as well as the state of body hydration and the distribution of liquids between the intracellular and extracellular compartments, potentially indicating metabolic and functional alterations in the presence of various types of pathologies [21]. For this study, the BIA data were collected through the bioimpedance system integrated into the same instrumentation used for the ICR sessions, called Quec Phisis 1 (Prometeo S.r.l., Padova, Italy). The measurement was performed as usual on the right side of the body of the patient, while he was lying on the same treatment bed in a supine and relaxed position. The 4 detection channels of the instrumentation were connected to the body of the patient using disposable 48x50 mm

F9060 ECG electrodes (FIAB SpA, Firenze, Italy), arranged in pairs at the level of the hand-wrist and ankle-foot areas, as shown in Figure 1.



**Figure 1.**  
Detail of the position of the 4 BIA detection electrodes on the body of the patient.

To limit the influence of environmental factors on NPRS and BIA measurements, both evaluations and treatments were always carried out in the same room, with constant artificial lighting and a fixed temperature of 21°C. The BIA evaluation at T0 was always performed on the patient after a period of adaptation to the supine lasting at least 5 minutes.

All patients underwent a total of 10 sessions of ICR over a period of one month, with a treatment frequency of one session every 48-72 hours. Each therapeutic session, with a fixed duration of 45 minutes, consisted of the application of ELF-MFs emitted by the same Quec Phisis 1 equipment used for the BIA assessment. The ICR device used consists of a flat diamagnetic bed surrounded by 4 resonant coils based on the principles of the Helmholtz resonator [25] connected to a generator of ultra-weak magnetic fields that can be modulated in both frequency and intensity and to a sensor for detecting the local geomagnetic field. The instrumentation is controlled through a portable PC equipped with a proprietary software dedicated to the operation of the instrumentation and the BIA assessment. The emitted magnetic field is automatically set by the proprietary software of the equipment, with frequency values up to 100 Hz and intensity between 5 and 15  $\mu$ T. These automatically modulated emission parameters are based on the answers given by the patient to a questionnaire about his general health status and on the items checked by the operator in a list of pathologies that could affect the patient.

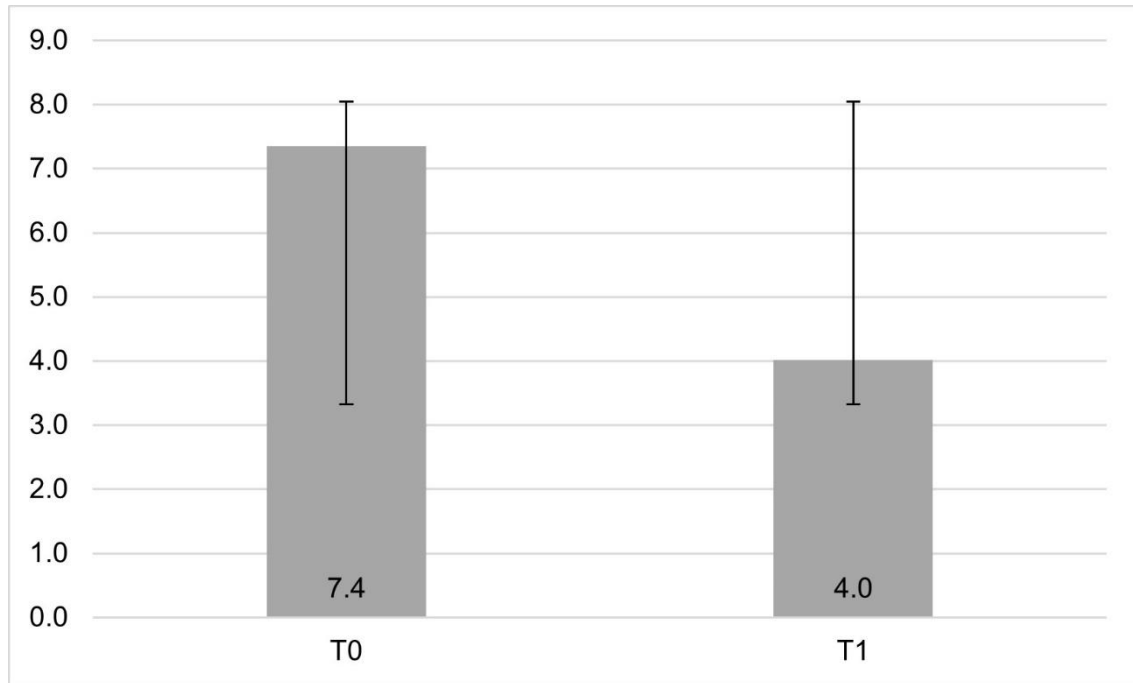
Both the collection of the assessment data and the treatment setting and execution were carried out for all the patients studied by the same, adequately trained, therapist.

For data analysis, longitudinal linear mixed models were applied through SAS 9.4 for Windows (SAS Institute Inc., Cary, NC, USA), using time since baseline as the time scale to identify factors associated with change over time of PA and NRS. Age and PA were considered as confounders; second order interactions were explored and reported if statistically significant.

### 3. Results

We observe a decrease in the NPRS value between the two times of the study. As matter of fact, the score change is  $-3.35 \pm 0.26$ , with a p-value <0.001 (Figure 2). The change in the NPRS values took

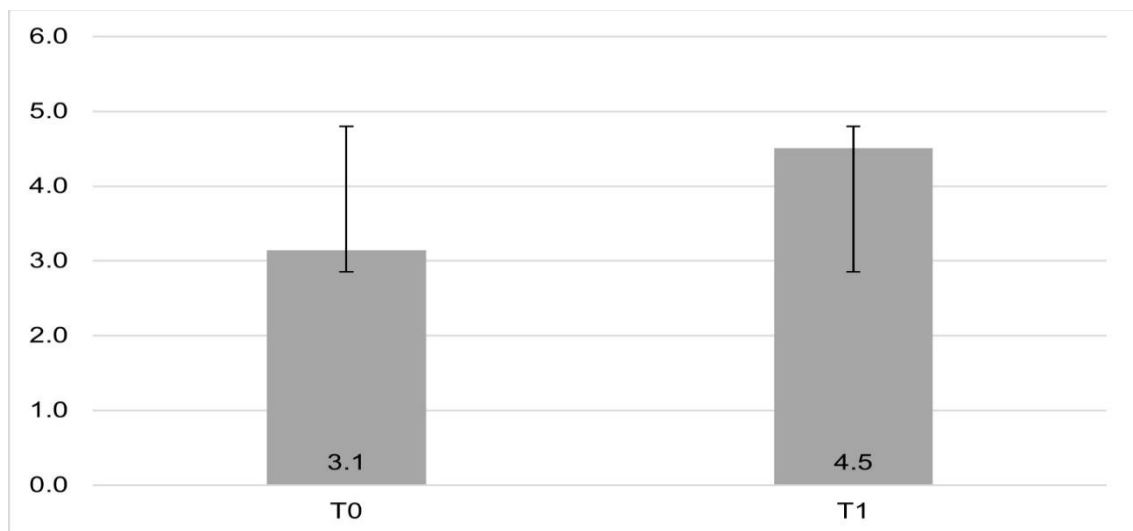
place independently from that of the PA and age, that did not reach a statistically significant role (p-value = 0.69; p-value = 0.25).



**Figure 2.**

Histogram that shows the variation of the mean NPRS values at times T0 (value equal to  $7.4 \pm 1.5$ ) and T1 (values equal to  $4 \pm 1.5$ ).

Regarding the PA value, it is possible to observe a slight increase of it between times T0 and T1. However, this increase does not reach statistical significance over the two time of the study (beta  $\pm$  SE:  $1.37 \pm 1.21$ , p-value = 0.26) (Figure 3). The model considers also age (p-value = 0.21).



**Figure 3.**

Histogram that shows the variation of the mean PA values at times T0 (value equal to  $3.1 \pm 3.6$ ) and T1 (values equal to  $4.5 \pm 3.2$ ).

#### 4. Discussion

Observing the data collected between T0 and T1 during this study, it is possible to highlight how the treatment with ICR is associated to a significantly reduced level of pain perceived by the patients according to the NPRS scale. Furthermore, a positive although not significant PA increase is highlighted.

The first finding of the present research is the confirmation of the analgesic properties of ICR. It has already been highlighted in the past by our experience and that of other authors that magnetic field therapies are able to reduce pain-related symptoms in pathological conditions that include, among others, chronic pain [14] visceral and somatic pain [26] oncological pain [27] and phantom limb pain [28]. The pain modulation induced by magnetic field therapies would appear to be determined by directly anti-inflammatory and immunomodulatory mechanisms [14, 26, 27, 29] as well as by the possible release of analgesic neurotransmitters [28].

Regarding the PA values detected between T0 and T1, it is possible to observe that, although the increase we recorded is not significant, the trend observed for the value is still consistent with an improvement in the clinical status of the observed patients. The definition of “normal” PA values is still a deeply debated topic in the clinical and diagnostic field. Some studies tend to classify as “normal” PA values that are approximately higher than  $6^\circ$  or  $7^\circ$  [30, 31] with a tendency to greater values in males and in young subjects (approximately in the range 18-39 years old) [31]. However, more recent evidence tends to lower these “normal” reference values, bringing them to around  $4.5^\circ$  and  $5^\circ$  [32, 33] depending on sex-age and taking also into account the basic health status of patients in hospitalization situations [33]. Since in our study, following the ICR treatments, the PA values increased from an average of  $3.14^\circ$  to a mean of  $4.51^\circ$ , it is possible to assert that the treatment induced a general, although statistically not significant, improvement of the PA values, which at the end of the observation were found to be closer to the normal healthy values indicated in the literature [30-33].

In any case, the data analysis highlighted that at the end of the treatment cycle it was not possible to detect a correlation between the trend of pain values recorded with the NPRS and that of the PA recorded with BIA. This result appears to be in contrast with the scientific literature, which attributes an increasing diagnostic and, above all, predictive value to PA in the presence of various types of pathologies [8-14, 33]. Although at first glance this lack of correlation could suggest a poor value of PA as a diagnostic tool in the presence of CMP, the fact that both values tend to improve following the application of ICR treatment protocol, albeit significantly only for pain, would seem to suggest that this misalignment could depend on intrinsic factors of the protocol.

It is possible that the discrepancies observed in the present study are attributable to some structural limitations of it. First, the observational nature of the study has placed clear limits in terms of sample selection and duration of the research. The sample size was objectively limited to the number of patients who turned to the study center and who received, from the evaluating medical doctors, the prescription of a therapeutic path with ICR, alternative to other classic CMP management protocols. Furthermore, since the data collection took place on patients with an evaluation and therapeutic path already determined, it was not possible to define a control group or follow-up assessments. However, the observational nature of the protocol allowed us to obtain values in a real clinical setting, possibly less artificial than those of an experimental setting, allowing at least to obtain preliminary data useful for designing specific experimental studies or larger observational studies on the topic. Any new studies on the topic should focus on larger samples, divided homogeneously by age group and sex, including control groups without treatment or comparisons between multiple treatment modalities and longer observation periods and with medium- and long-term follow-ups.

#### 5. Conclusions

This study confirmed the effectiveness of ICR in reducing pain perceived by patients with CMP. Furthermore, it was possible to observe a positive but non-significant modification of the PA value detected by BIA. The misalignment in the significance of the trend of pain and PA did not allow to



confirm a direct correlation between the two factors, making it necessary to further clarify the diagnostic role of BIA, and in particular of PA, in the clinical and diagnostic field. Since the usefulness of BIA as an element of evaluation in the presence of pathologies is still widely debated, this brief observational research lays the foundation for future studies on the topic of the use of BIA as an assessment tool for musculoskeletal pathologies such as CMP. In light of our results, a more extensive and structured setting would be required to draw clear conclusions on the topic. In fact, according to our observations, the PA remains a promising but still not easily interpretable diagnostic tool in the musculoskeletal field, which could benefit from observations conducted on larger samples and over a longer period of time, to clearly identify its potential and limits.

### Transparency:

The authors confirm that the manuscript is an honest, accurate, and transparent account of the study; that no vital features of the study have been omitted; and that any discrepancies from the study as planned have been explained. This study followed all ethical practices during writing.

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