

The Efficiency of Capacitive/Resistive Monopolar Radiofrequency 448kHz (INDIBA®) in Patients with Chronic Lateral Elbow Tendinopathy: Pilot Study

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Abstract

Purpose: The present study aimed to examine the effect of Capacitive/Resistive Monopolar Radiofrequency 448kHz (CRMRF) in patients with chronic lateral elbow tendinopathy (LET).

Participant(s) and Methods: 20 patients with chronic LET were divided into two groups and received a supervised exercise protocol, based on progression and neuroplasticity, as well as were treated with one of the two under supervision protocols of INDIBA®; 448kHz CRMRF either with thermal output power in continuous standard wave or thermal output power in continuous modulated wave) of INDIBA. Measurements took place at the start and the end of the treatment, as well as the 1st and the 3rd month after the treatment.

Results: Both teams exhibited statistically significant improvements when measuring the outcome of the treatment, both as comparatively and individually. Pain and kinesiophobia were reduced, and functionality and strength were increased.

Conclusion: 448 kHz CRMRF with continuous standard wave might be a better approach in chronic LET treatment than modulated current. Despite the excellent results of the combination of supervised exercise and CRMRF 448kHz, the design of the study does not allow the results to be generalized.

Keywords: Lateral Elbow Tendinopathy; Exercise; Capacitive Resistive Monopolar Radiofrequency 448kHz.

Abbreviations

LET: Lateral Elbow Tendinopathy; CRMRF: Capacitive Resistive Monopolar Radiofrequency; NSAID: Non- Steroidal Anti-Inflammatory Drug; PRP: Platelet-Rich Plasma Injections, ECSW: Extracorporeal Shock-Wave Therapy; LLLT: Low-Level Laser Therapy; RCT: Randomised Control Trial; VAS: Visual Analogue Scale; PRTEE: Patient Rated Tennis Elbow Evaluation; CAP: Capacitive; RES: Resistive; TNT: Tendon Neuroplastic Training

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Introduction

Lateral elbow tendinopathy (LET) is the most common chronic disease affecting the elbow joint [1]. Almost 40% of the population will exhibit pain in the lateral epicondyle of the dominant arm at least once in their lifetime [2,3]. Most of these people tend to work in physically laborious jobs carrying out repeated movements with or under great force and vibrations; adopting awkward position [2,3]. LET affects 1-3% of the general population [2,4]. LET is positively correlated with age, it ranges between 35 to 60 years old [4,5]; uses to be manifest mainly at 40 years old [4,6,7]. It can be defined as chronic when the symptoms persist over 4 weeks [6,8-11].

Dealing with LET is imperative, since the number of patients is constantly rising. Physiotherapy is one of the most frequent interventions [12]. There are numerous therapy suggestions [1,13], such as braces, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, autologous blood injections, platelet-rich plasma injections (PRP), extracorporeal shock-wave therapy (ECSW), low-level laser therapy (LLLT), acupuncture, cryotherapy, thermotherapy [14-16], which comes in accordance with the complexity of the disease [1]. Systematic reviews do not agree on which treatment approach is the safest and best [14,15] or even whether physiotherapy itself is the ideal intervention [16].

A supervised exercise program is one of the first choices of a physiotherapy program for the conservative treatment of LET without it being the gold standard of dealing with the disease [17]. It is recommended to be combined with another intervention to achieve maximum effectiveness and reduced therapy time [17]. However, the best combination has yet to be discovered [11,17].

Capacitive Resistive Monopolar Radiofrequency at 448kHz is a relatively new therapeutic approach that is being used worldwide by clinicians for the management of LET [18]. The primary effect of 448kHz CRMRF is the increment of superficial and deep tissue temperature [18,19]. One of the main characteristic of this technique is that it can be applied in different modes as required (Thermal, non-thermal or sub-thermal output power with continuous standard or modulated wave, with or without tools, during or apart from the exercise program) [11,18-23]. Despite the fact that electrophysical modalities that use the 448kHz CRMRF technology are available in the market, their therapeutic effectiveness is not scientifically proven [18,19].

Purpose of the Study

The primary purpose of the present study was to investigate whether this therapy in combination with a supervised exercise program would be efficient to reduce pain and kinesiophobia and would increase grip strength and functionality in patients with chronic LET. Secondary aim was to assess the best approach to LET treatment taking into count that CRMFRF at 448kHz can be used at a continuous standard wave or at a continuous modulated wave.

Materials and Methods

This trial was a double-blind RCT. Informed written consent was ensured prior to the assessment, along with a general health and medical history form. Sessions took place in the Laboratory of Neuromuscular and Cardiovascular Study of Motion (LANECASM) of West Attica University. This trial was approved by the Bioethics Committee of the West Attica University (15/10/2021- 86886).

Twenty patients participated in the trial (age: ± 46). Inclusion and exclusion criteria were set according to Stasinopoulos protocol [9-11,24]. Patients were divided into two groups. Both groups received twenty sessions (5 per week). Their treatment included a supervised exercise protocol and a 448kHz CRMRF session (heating effect). The exercise protocol was common for both teams. Group A received

448kHz CRMRF with a continuous standard wave; Group B received 448kHz CRMRF with a continuous modulated wave. Application parameters were determined by the manufacturer, INDIBA© (Indiba S.A., Barcelona, Spain).

CAP electrode was applied for 5' on biceps brachii, triceps brachii, and wrist extensors. RES electrode was applied for 10' on the affected area. Lastly, CAP electrode was applied for 5'. The return electrode was placed under the subject's elbow.

The exercise protocol consisted of 3 sets of 15 repetitions of slow progressive exercises of the wrist extensors at each treatment, with a minute rest interval between each set [11,23]; static stretching exercises of the wrist extensors- 3 times before and 3 times after the exercises, lasting 30-45" 25-28 with a 30-second rest interval between each repetition [28]; 2 sets of 12 repetitions of the scapular and rotator cuff muscle [10,11,29], upper trapezius, rhomboids, serratus anterior, levator scapulae [10,11,17,23,30] and supinator [31].

Wrist extensors were strengthened using the pattern isometric (10") 32,33- eccentric - concentric contraction [10,11,23], which was ensured by the use of a metronome application on a portable device (Metronome Beats, Stonekick; 6 beats per minute) [11,23]. The elbow was extended on the therapy surface [11,23]. Participants were informed to continue the exercise even if their pain was mild (< 4 on VAS). However, they were informed to stop the exercise if it became disabling (> 8 on VAS) [8,9]. When participants were able to carry out the exercise program without experiencing any discomfort or pain, free weights were used to increase the load [11].

All patients were instructed to use their arm as they normally would during the course of the study avoiding activities that would irritate the elbow such as knitting, lifting, driving a car, using a screwdriver, grasping, and handwriting [11]. They were informed to refrain from taking painkiller drugs or other conservative treatment throughout the course of the study [11]. Finally, communication and interaction (verbal and non-verbal) between the therapist and patient were kept to a minimum [11,17,34]. Each patient was evaluated at the baseline (week 0), at the end of treatment (week 4), one month (week 8), and three months (week 16) after the end of treatment in order to see the intermediate effects of the treatments. Participants were assessed on pain (VAS, PRTEE- Greek), function (VAS, PRTEE- Greek, Jamar© hand dynamometer), strength (Jamar© hand dynamometer - pain-free grip strength) and kinesiophobia (Tampa Scale - Greek) [35-43].

Results and Discussion

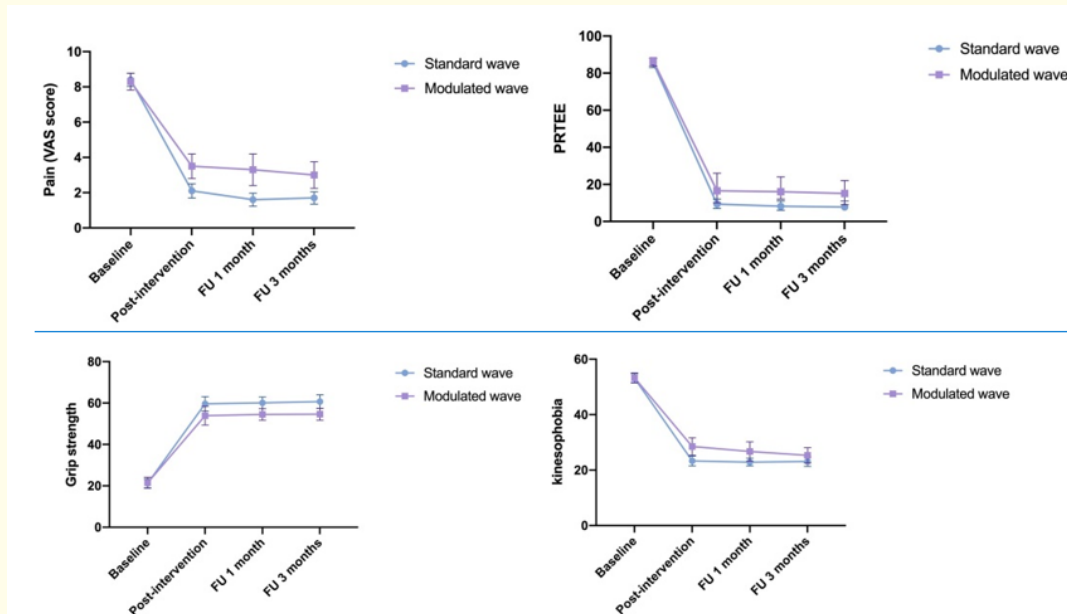
The age is 35 - 51 years (SD:5,03) for Group A, and 43-52 (SD: 2,82) for Group B. The arm that is affected is the dominant one for all participants. There are no statistically significant differences between the group concerning the characteristics ($p < 0,05$).

The results indicate that statistical significant changes were presented when comparing the two groups at the end of the treatment, 1 and 3 months after the treatment. However, kinesiophobia of Group A did not differ significantly to ($p = 0,052$) kinesiophobia of Group B 3 months after the end of the intervention.

In addition, each group's variables were differentiated significantly when comparing the results of the assessments of the start of the intervention to the end of it and 1 and 3 months after the intervention accordingly ($p < 0,05$). (Graphs 1-4)

However, the percentages of continuous standard wave were greater. Group A had better results on pain, kinesiophobia, grip strength and functionality. Pain for Group A decreased by 75% and kinesiophobia by 56%, whereas grip strength increased by 72% and functionality by 89%, accordingly, from the start of the trial to the last assessment. Group B presented 58% pain reduction and a decrease of 47% in kinesiophobia; whereas grip strength for these patients increased by 61% and functionality by 81%.

The score of TSK was marginally not significantly different when comparing the two groups in the end of the trial. The important thing is that kinesiophobia reduced in both groups. According to systematic reviews of Huang., et al. and Xu., et al. [42,44] a program that has



Graphs 1-4: Pain Functionality Strength & Kinesiophobia changes during assessments.

more than one intervention is rather effective to an one- dimensional intervention. Judging by the result we assume that kinesiphobia did not differ between the waves not because it is not related to the nature of the wave, but with the result of the intervention (decrease in pain and increase of functionality) and participants’ psychological state.

INDIBA® CT8 produces radiofrequency in different modes, with standard and modulated waves. When the wave is modulated, there is a reduction of voltage and increase of electric charge. However, the thermal charge is automatically defined by the device at 40% maximum. According to the manufacturer the results are the same, however, our results prove otherwise, so we assume it is the reduction of the voltage that reflects on a lesser thermal effect. In clinical practice, this is hard to be proven, since research in labs has been conducted on animals that have different thermoregulation [18]. It is undoubted though, that there is a difference between SWT (Short Wave Therapy) and 448kHz CRMRF, since, despite the fact that they use the same technology, there is no loss of heat due to the energy transfer through the coupling medium and the different operating frequency (448kHz vs. 27,12MHz) [11,17,18,20-22].

The main effect of 448kHz CRMRF is tissue hyperthermia superficially and deeply [19]. Heat increases metabolic rates, vasodilation and blood flow promoting tissue recovery and providing pain relief by increasing the pain threshold [45]. Hence, Piponas and Stasinopoulos and Stasinopoulos [22,23] used it to treat acute musculoskeletal conditions. Tendons in LET do not present inflammation; however, adjacent tissues may be inflammatory [18,19].

Research data for this kind of radiofrequency is really limited, since it has mainly been examined on animals and healthy population [18,20,21]. Musculoskeletal conditions that have been examined and had statistical significant results are knee osteoarthritis [46], acute ankle sprain [22], rotator cuff tendinopathy [20,21], acute LET [23]. Avendano-Coy, *et al.* examined sub-acromial pain and did not find statistical differences on pain and functionality [47].

In this trial, CRMRF was used according to manufacturer's guidelines. However, in clinical practice, the last part of capacitive electrode in non-thermal mode is omitted [18,19]. 448kHz CRMRF is a dose response therapy [20,21]; however, each person perceives temperature differently, since temperature receptors are sensitized from 30 - 35°C, which is quite a range [48].

There are various protocols [49-55]. However, in this trial, the Stasinopoulos protocol was followed [10,17,27,28]. Under supervision protocols present better results faster [17,28,57-59]. Exercise, according to Karanasios, *et al.* (2021), seems to be the best intervention amongst others; however, certainty degree is low [60]. Isometric- eccentric- concentric contraction was used [56] since, the earlier the isometrics begin the better and more long-term the results are [32]; eccentrics present the most beneficial effect when combined with other interventions [59,61,62]. Shoulder and scapula and supinator muscle strengthening was done because muscle weakness affects the joint mechanism and stability [29-31,67].

Exercise was done by the sounds of metronome. This affects neuroplasticity [11,63-65], the relationship between pain and changes in motor control. Tendon neuroplastic training; TNT, affects the central sensitization that occurs in chronic pain [66].

According to Raman, *et al.* there is great heterogeneity in studies concerning the number of sets, repetitions, time break, frequency and duration [61]. This trial comes in accordance to Chen and Baker's systematic review for eccentric exercise; they concluded that the exercise for LET should be of high dose, once a day, 3 sets, 10 - 15 repetitions [59]. The duration differs; 4 vs. 6 weeks; but it has been tested as effective [9,28,58].

Patients continued the exercise if their pain was 4 to 8/10 (point where they ceased exercise) on VAS scale to avoid central sensitization, due to fear of pain [45] and the low risk of reinjury, due to self-check [28,59]. However, pain is a psychophysiological behavior unique for each person (George Engel's model) [68].

Participants were instructed to avoid heavy activities during the course of the trial, however, we cannot be sure whether this was followed [11,34]. Communication between participants and therapist was kept to minimum [11], to avoid Hawthorne effect, however, that is a variable that cannot be fully controlled since physiotherapy demands physical contact and involves the deep relationship between movement, perception, and action [69].

Assessments were conducted three months after the trial, so only the intermediate effect of the therapy was evaluated. It is recommended that future studies should focus on long-term results, as well.

The PRTEE questionnaire is the ultimate tool for assessing functionality in LET and should be used in every future study [70]. Hand-grip strength should also be part of LET assessments. JAMAR® Hydraulic Hand Dynamometer used by this trial is the gold standard for measuring hand-grip strength [70,71].

Another novelty of this trial is the use of the TSK scale. To our knowledge, no other study in Europe has used kinesiophobia as a variable. Persisting pain can cause changes in behavior for both because of physical and psychological reasons [72]. Various psychological factors, such as pain, depression, anxiety, catastrophology, affect pain and functionality [73,74]. In addition to that, hypervigilance to stimuli can cause increase of dysfunction, avoidance of limb use and depression [75]. In this trial, there was no correlation between kinesiophobia, pain, functionality and hand-grip strength. However, kinesiophobia followed pain's decrease path. Future use of kinesiophobia in LET studies is strongly suggested.

The number of participants was calculated arbitrarily. Other trials' sample (10-75 participants per group) were taken into consideration [76,77]. However, Consolidated Standards of Reporting Trials (CONSORT) reports explicitly that the sample should be calculated not chosen [77-79].

Conclusion

The present study was novel as it examined the effect of continuous modulated and standard 448kHz CRMRF therapy and exercise on patients with chronic LET. Its novelty lies on the assessment of the different way Standard wave in this trial proved to be more effective than the modulated one.

Its application was decisive in reducing pain and kinesiophobia and increasing handgrip strength and functionality when comparing the CRMRF protocols-continuous standard and continuous modulated; thermal output power- with each other and themselves alone during the assessments.

Tendons' damage cannot be restored but pain, functionality and the relevant assessments can be differentiated [64]. We assume it is the high dosage under supervision TNT, which, in combination with the application of 448kHz CRMRF, made the results not only change but improve more even after 3 months. The outcomes suggest the conduction of a main study with longer period of remeasurement. Research on cost- effectiveness should be conducted, since cost is a factor of choosing treatment modalities. Last but not least, it is advised that future studies conclude about the parameters of the exercise itself and 448 kHz CRMRF, as well.

Conflict of Interest

None.

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