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Research Article

# The Effectiveness of Thermal Mode of 448 kHz Capacitive Resistive Monopolar Radiofrequency in the Continuous Wave in Patients with Chronic Lateral Elbow Tendinopathy. A Pilot Clinical Trial

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## Abstract

The aim of the present clinical trial was to compare the clinical results of the use of an exercise program with those of an exercise program and thermal (thermia or hyperthermia) mode of 448 kHz Capacitive Resistive Monopolar Radiofrequency in the continuous wave in patients with chronic lateral elbow tendinopathy. Patients were allocated to two groups. Pain, function, strength, and kinesiophobia were measured. An exercise programme and thermal (thermia or hyperthermia) mode of 448 kHz Capacitive Resistive Monopolar Radiofrequency in continuous wave, had reduced the pain and kinisiophobia and improved function and strength in patients with chronic lateral elbow tendinopathy at the end of the treatment and at the follow-ups. Future well-designed randomised controlled clinical trials are needed to establish the effectiveness 448 kHz Capacitive Resistive Monopolar Radiofrequency in the management of chronic lateral elbow tendinopathy.

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

## 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].

Although an exercise program is an effective treatment approach, a supplement to the exercise program should be found to reduce the treatment period [18-23]. One such modality is 448 kHz Capacitive Resistive Monopolar Radiofrequency (CRMRF) which is a relatively new treatment approach, but it is reported to be used by clinicians worldwide. A previous pilot trial showed that the thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave, had reduced the pain and improved function and strength in patients with chronic LET at the end of the treatment and at the follow-ups [21]. To our knowledge, there have been no studies to investigate the effectiveness of the thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave as a supplement to an exercise program in the management of chronic LET. Therefore, the aim of the present study was to compare the clinical results of the use of an exercise program with those of an exercise program and thermal (thermia or hyperthermia) mode of 448 kHz CRMRF in continuous wave in patients with chronic LET.

## Participants and Methods

Twenty patients participated in the trial. Inclusion and exclusion criteria were set according to Stasinopoulos protocol [9-11,24]. This trial was a double-blind pilot 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).

Patients were divided into two groups. Both groups received a supervised exercise protocol total of twenty sessions (5 per week). Group A received 448kHz CRMRF with a continuous standard 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, however, 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 two months (week 12) after the end of treatment in order to see the intermediate effects of the treatments.

Participants were assessed on pain (VAS [35,36], PRTEE – Greek [37,38], function (VAS [35,36], PRTEE- Greek [37,38], Jamar© hand dynamometer [39,40], strength (Jamar© hand dynamometer - pain-free grip strength [39,40] and kinesiophobia (Tampa Scale – Greek [41-44].

SPSS (version 27.0) was used for statistical analyses. The Kolmogorov- Smirnov test was used to test the sample distribution. Paired sample t-test was performed to identify statistically significant side-to-side differences (within the group) for samples that followed a normal distribution and the Wilcoxon test for samples that did not follow a normal distribution. Independent t-test and Mann- Whitney test were performed to analyze the mean comparison of the two groups for samples that followed normal distribution or not, accordingly. P values <0.05 were considered to be statistically significant.

## Results

At baseline there were more men than women in the study groups (three more in total). The mean age of the patients was about 47y, and the duration of LET was about 6 months. LET was in the dominant arm in 80% of patients. There were no significant differences in mean age ($p > 0.0005$ by independent t-test) or the mean duration of symptoms ($p > 0.0005$ on independent t-test) between the groups. The patients had received drug therapy as previous treatment. All patients were manual workers.

Baseline VAS was 8.45 (95% CI 8.23-8.89) for the entire sample. There were no significant differences between the groups for baseline VAS ($p>0.05$ on independent t-test) At week 4, there was a decline in VAS of about 6.8 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 5.4 units in the exercise programme group compared with the baseline ($p < 0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 8 and 12 ($p > 0.0005$ independent t test) (Figure 1).

Baseline PTREE was 86.6 (95% CI 83,4-89,5) for the entire sample. There were no significant differences between the groups for baseline PTREE ($p > 0.05$ on independent t-test) At week 4,

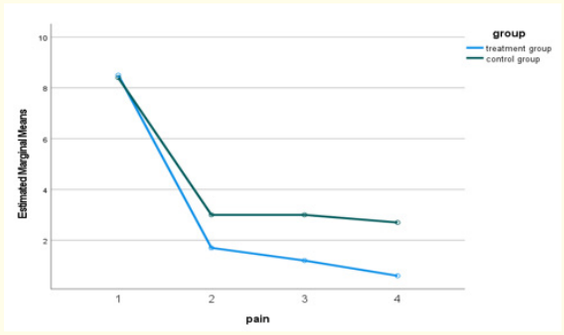


**Figure 1:** Pain change during assessments.
Treatment group: Exercise programme and 448 kHz CRMRF in continuous.
Control group: Exercise programme.

there was a decline in PTREE of about 77.7 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 74.7 units in the exercise programme group compared with the baseline ($p < 0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 8 and 12 ($p > 0.0005$ independent t test) (Figure 2).

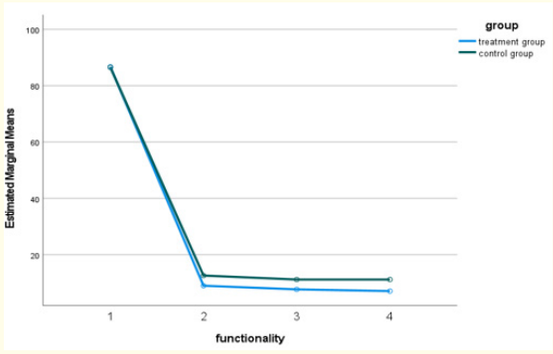


**Figure 2:** Functionality change during assessments.
Treatment group: Exercise programme and 448 kHz CRMRF in continuous.
Control group: Exercise programme.

Baseline Strength was 22.5 (95% CI 19,78-24,8) for the entire sample. There were no significant differences between the groups for baseline strength ($p > 0.05$ on independent t-test) At week 4, there was an increase in strength of about 40.5 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 34.9 units in the exercise programme group compared with the baseline ($p < 0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 8 and 12 ($p > 0.0005$ independent t test) (Figure 3).

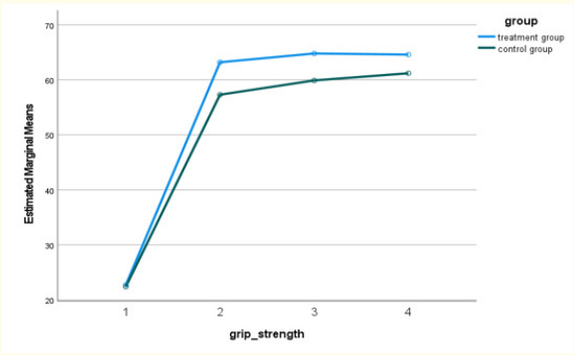


**Figure 3:** Strength change during assessments.
Treatment group: Exercise programme and 448 kHz CRMRF in continuous.
Control group: Exercise program.

Baseline Kinesiophobia was 55.1 (95% CI 52.4-58.3) for the entire sample. There were no significant differences between the groups for baseline strength ($p > 0.05$ on independent t-test) At week 4, there was a decline in kinesiophobia of about 33.6 units in the exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave group and 31.1 units in the exercise programme group compared with the baseline ($p < 0.0005$, paired t test). There were significant differences in the magnitude of reduction between the groups at weeks 8 and 12 ($p > 0.0005$ independent t test) (Figure 4).

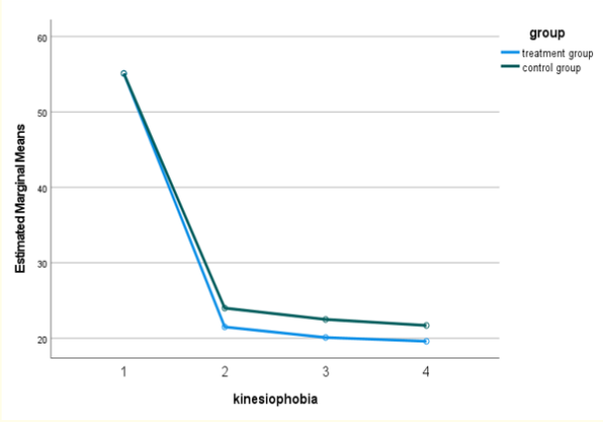


**Figure 4:** Kinesiophobia change during assessments.
Treatment group: Exercise programme and 448 kHz CRMRF in continuous.
Control group: Exercise programme.

## Discussion

The results obtained from this controlled pilot clinical trial are novel; as to date, there have been no data comparing the effectiveness of an exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave and an exercise

programme and placebo 448 kHz CRMRF for the reduction of pain and improvement of function and strength in chronic LET. The exercise programme and thermal (thermia or hyperthermia) of 448 kHz CRMRF in continuous wave produced the largest effect at the end of the treatment and at the follow ups.

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. Heat increases metabolic rates, vasodilation and blood flow promoting tissue recovery and providing pain relief by increasing the pain threshold [46]. Hence, Piponas and Stasinopoulos [22] and Stasinopoulos [23] used it to treat acute musculoskeletal conditions. As a matter of fact, tendons in LET do not present inflammation; however, adjacent tissues may be inflammatory [18,19]. Fousekis., *et al.* (2020) found that 448kHz CRMRF increased the temperature of quadriceps skin [10],6% for 164' after the session [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 statistically significant results are knee osteoarthritis [47], 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 [48].

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]. However, it is supposed to have a draining role and the protocol: CAP RES CAP, should be followed to promote ion mobilization to the return electrode. 448kHz CRMRF is a dose response therapy [20,21]; however, each person perceives temperature differently, since temperature receptors are sensitized from 30-35oC, which is quite a range [49].

There are various protocols, but the ones that prevail come from Pienimaki., *et al.* [50]; Vicenzino [51-53]; Solveborn [54-56]. However, in this trial, the Stasinopoulos protocol was followed; under supervision, with isometric-eccentric [1,67] concentric exercises, strengthening of arm and shoulder, scapula and supinator and static stretches [10,17,27,28]. Under supervision protocols present better results faster [17,28,58-60]. Exercise, according to Karanasios., *et al*, seems to be the best intervention amongst others; however, certainty degree is low [61]. Isometric- eccentric- concentric contraction was used [57] since, the earlier the isometrics begin the better and more long-term the results are [32]; and eccentrics present the most beneficial effect when combined with other interventions [60,62,63].

Exercise was done by the sounds of metronome. This affects neuroplasticity [11,64-66], the relationship between pain and changes in motor control. Tendon neuroplastic training; TNT, affects the central sensitization that occurs in chronic pain [67]. Shoulder and scapula and supinator muscle strengthening was done because muscle weakness affects the joint mechanism and stability [29-31,68].

According to Raman., *et al*, there is great heterogeneity in studies concerning the number of sets, repetitions, time break, frequency and duration [62]. 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 [60].

The duration differs; 4 vs. 6 weeks; but it has been tested as effective [9,28,59]. 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 [46] and the low risk of reinjury, due to self-check [28,60]. However, pain is a psychophysiological behavior unique for each person (George Engel's model) [69].

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 [70].

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, according to Bateman., *et al*, is the

ultimate tool for assessing functionality in LET and should be used in every future study [71]. Handgrip 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 [71,72]. 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 [73]. Various psychological factors, such as pain, depression, anxiety, katastrophology, affect pain and functionality [74,75]. In addition to that, hypervigilance to stimuli can cause increase of dysfunction, avoidance of limb use and depression [76]. 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 arbitrary. Other trials' sample (10-75 participants per group) were taken into consideration [77,78]. However, Consolidated Standards of Reporting Trials (CONSORT) reports explicitly that the sample should be calculated not chosen [78-81].

Tendons' damage cannot be restored but pain, functionality and the relevant assessments can be differentiated [64]. This trial's variables changed results radically; 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 2 months. The outcomes suggest the conduction of a main study with longer period of remeasurement.

## Conclusion

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.

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