# Pulsed High Frequency (27MHz) Electromagnetic Therapy for Persistent Neck Pain

## A Double Blind, Placebo-Controlled Study of 20 Patients

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ABSTRACT: In the majority of patients with neck pain, symptoms will resolve spontaneously or quite quickly in response to therapy. However, some patients' symptoms persist for a long period, irrespective of therapy. In this study, 20 patients with persistent (greater than 8 weeks) neck pain were enrolled in a double blind, placebo-controlled trial of low energy, pulsed electromagnetic therapy (PEMT)—a treatment previously shown to be effective in soft tissue injuries. For the first 3-week period, group A (10 patients) received active PEMT units while group B (10 patients) received facsimile placebo units. After 3 weeks, both pain (visual analogue scale ($P<.023$) and range of movement ($P<.002$) had improved in the group on active treatment compared to the controls. After the second 3 weeks, during which both groups used active units, there were significant improvements in observed scores for pain and range of movement in both groups. PEMT, in the form described, can be used at home easily in the treatment of patients with neck pain. It is frequently successful and without side effects.

### Introduction

Persistent neck pain is a common complaint of middle aged and elderly patients.[1] The two most frequent causes of such pain are cervical spondylosis and trauma. Cervical spondylosis is an extremely common radiologic finding. Schmorl and Junghans found osteophytes in 90% of men over the age of 50 years and in women over the age of 60 years.[2] Many patients with radiologic changes of cervical spondylosis are asymptomatic. When radiographic changes are present, they may not be the cause of the symptoms.[3] Rear end collisions, causing soft tissue injuries to the neck, constitute about 20% of all vehicle accidents.[4] These are often referred to as "whiplash" injuries. Neck pain after these events tends to be persistent, lasting up to 6 months in 75% of patients[5] and up to 2 years in 66% of patients.[6] In another study, 35% of patients were symptomatic at 6 months and 26% at 1 year.[7]

Treatment of patients with persistent neck pain may be difficult. In a trial of soft collars, postural exercise instruction, traction, placebo traction, and placebo medication use in patients with neck pain, no difference in outcome was found between the treatment groups.[8] Furthermore, it was found that three quarters of the patients had minimal symptoms and signs after 4 weeks follow up, indicating that neck pain is a self-limiting condition in most cases. There have been surprisingly few other therapeutic studies in patients with chronic neck pain. None shows any significant improvement in treatment outcome when compared to the modalities mentioned earlier.

Galvani discovered in 1794 that there is a "current of injury," an electrical charge generated at the site of damage in living organisms.[9] Matthews, in 1903, found potential gradients along the surface of regenerating hydroids and proposed that natural electrical fields might influence tissue repair.[10] In the late 1950s and early 1960s, new interest in this area arose when Becker,[11] Basset and Becker,[12] and Fukada and Yasuda[13] reported

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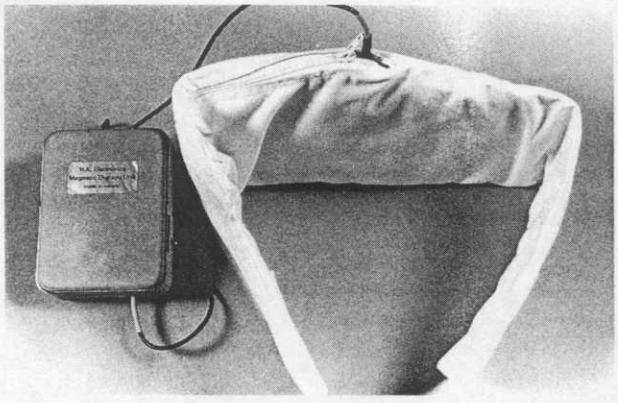
**Figure: PEMT cervical collar and attached battery-operated power source.**



bioelectrical fields associated with amphibian limb regeneration and bone dynamics.

Over the last 30 years, increased attention has focused on the use of electrical signalling to stimulate tissue healing, especially in cases in which conventional therapy is ineffective. Pulsed electromagnetic therapy (PEMT) has been shown to accelerate fracture healing in refractory cases[14,15] and has been used to treat failed joint arthrodesis[16] and avascular necrosis.[17] Low frequency (40 to 70 Hz) medium power PEMT has been used in these trials. Higher frequency PEMT devices have been reported to accelerate wound healing,[18] dental alveolar healing,[19] and nerve regeneration.[20] Symptomatic relief and accelerated healing have also been reported in studies of patients with ankle ligament injuries[21] and rotator cuff tendonitis.[22]

Low power PEMT would deliver approximately 1.5 $mW/cm^2$, while medium power would deliver approximately 0.5 $watt/cm^2$ at the skin's surface. Nagelschmidt, in 1940, proposed, in relation to the therapeutic effectiveness of short wave diathermy, that "there must be some other effect, not as yet realized, to account for the phenomena which could not be reasonably attributed to heat alone."[23] In this study, we chose low power pulsed short wave (approximately 27 MHz) because of its safety over prolonged periods,[24] allowing a safe 8 hour/day minimum treatment duration, with minimal inconvenience for patients treated in their homes. To assess the impact of treatment in patients with persistent neck pain, a double blind randomized controlled trial was undertaken using PEMT.

## Patients and Methods

Twenty consecutive patients, over the age of 18 years with neck pain of greater than 8 weeks duration, and unresponsive to at least one course of nonsteroidal antiinflammatory drugs, were invited to enter the study. The study was approved by the Hospital Ethical Committee. Each patient was given a soft cervical collar (Figure), within which was a flexible pulsed electromagnetic therapy unit. During the study, patients were asked to wear their collars for 8 hours daily. Patients with prolapsed cervical discs and those with neoplastic, inflammatory, infective, or metabolic diseases of the cervical spine were excluded from the trial. All patients entering this study were on a regular analgesic regime of either a nonsteroidal antiinflammatory drug or simple analgesics, or a combination, for 4 weeks prior to study entry.

## Study Design

The 20 patients who entered were attending either the rheumatology outpatients or the physiotherapy department. As patients were enrolled in the study, they were randomly assigned a collar, the status of which (ie, whether active or a placebo facsimile unit) was unknown to both the patient and the principal investigator. The units were supplied, each bearing an identity number, by H & K Electronics (Dublin, Ireland). Thus, by allocation of a collar, the patient was randomly entered into one of the two equal groups of 10. Group A received two different active units each for 3 weeks. The total study duration was 6 weeks. Those in group B received placebo facsimile units for the first 3 weeks and active units for the second 3-week period. A strict double blind protocol was adhered to throughout the study. Patients were asked to reduce analgesics if they felt they no longer needed them. Patients were not allowed to change their nonsteroidal antiinflammatory drug during the study. If they had pain they were instructed to take two paracetamol tablets (maximum eight in 1 day). The duration of the study was determined by the response rate we had observed in other patients in a small open study. Patients were reviewed at weekly intervals during the study.

## Assessment

At entry, each patient had cervical spine radiographs, full blood count, erythrocyte sedimentation rate, and biochemical profile performed. At each visit, neck movement and pain were assessed. Pain was assessed by determining analgesic use on a visual analogue scale (10 cm horizontal line). Patients were asked to assess their pain over the preceding 48 hours. Neck movement was graded as full, two-thirds normal, one-third normal, or absent. Thus, a patient would score a maximum of six if they had a full range of passive movement in all six directions tested: flexion, extension, lateral flexion to the right and left, and rotation to the right and left. At 3 weeks and at 6 weeks, patients were asked to make a

TABLE 1
DEMOGRAPHIC DATA ON PATIENTS AT PRESENTATION

| | Group A | Group B |
|---|---|---|
| No of patients | 10 | 10 |
| Sex (M:F) | 7:3 | 5:5 |
| Patients mean age (yrs) | 38 | 47 |
| Range | 21-70 | 26-69 |
| Mean duration symptoms (mos) | 22 | 17 |
| Range | 2-60 | 2-64 |
| X-ray changes | | |
| Present:Absent | 6:4 | 6:4 |
| Traumatic onset | 5 | 5 |

global assessment of their progress over the previous 3 weeks. There were nine options from which to choose: worst possible, much worse, moderately worse, mildly worse, no change, mildly better, moderately better, much better, and completely well.

A voltmeter reading of the unit's battery power source was made at the 3 and 6-week reviews to assess compliance. Reduction in battery voltage correlates with the duration for which the unit was switched on. It was assumed that the groups were evenly matched for the eventuality of the unit being switched on while not being worn by the patient, though this possible discrepancy could not be measured in this study.

## Type of PEMT

The units consisted of miniaturized, pulsed, short wave, diathermy generators incorporated in soft collars, weighing approximately 100 g. These generators produce a pulsed magnetic field in the treatment area with a mean power of 1.5 mW/cm$^2$ at the patient's surface. Each unit was powered by two 9-volt batteries. The nominal frequency was 27 MHz. The pulse burst width was 60 microseconds and the repetition frequency was 450 cycles per second.

## Statistical Methods

In view of the small sample size, nonparametric statistical analysis was performed using the Wilcoxon matched pairs signed ranks test.

## Results

All of the patients who entered into the study completed it. The patient data are presented in Table 1. The mean age of patients in group A was slightly greater and the duration of symptoms slightly longer than in group B, although the range was very similar. Degenerative changes were present on the radiographs of six patients in each group. Five patients in each group reported trauma as the initiating event of their pain. There was no significant difference between the two groups at the beginning of the study except in the case of analgesic and antiinflammatory tablet consumption.

TABLE 2
RESULTS OF PAIN AND RANGE OF MOVEMENT DURING THE STUDY (MEDIAN VALUES GIVEN)

| | Group A | | | Group B | | |
|---|---|---|---|---|---|---|
| Treatment | | Active | Active | | Placebo | Active |
| Week | 0 | 3 | 6 | 0 | 3 | 6 |
| Pain (VAS CM) | 7.0 | 4.0 | 2.0 | 6.75 | 5.5 | 3.0 |
| Change from baseline ($P$) | | $<.005$ | $<.012$ | | NS | $<.015$ |
| Group A vs Group B ($P$) | | $<.023$ | NS | | $<.023$ | NS |
| Range of movement | 3.6 | 4.1 | 4.8 | 3.3 | 3.45 | 4.6 |
| Max score = 6 | | | | | | |
| Change from baseline ($P$) | | $<.008$ | .018 | | NS | $<.008$ |
| Group A vs Group B ($P$) | | $<.02$ | NS | | $<.02$ | NS |
| Pill count | 5 | 4 | 1 | 2.5 | 2.0 | .5 |
| Change from baseline ($P$) | | $<.018$ | $<.008$ | | NS | $<.028$ |

At the beginning, the median pain score for the active group was 7.0 and for the placebo group it was 6.75. The groups did not differ significantly at this point. Following 3 weeks of PEMT, the median pain score fell in group A to 4.0 ($P < .005$), whereas there was no change in the placebo group (median 5.5). In the second half of the trial, when both groups received active therapy, there was a further drop in the pain score of group A ($P < .012$). Those treated initially with placebo units also showed a drop in their pain scores (median 3.0) during their initial 3 weeks of active PEMT ($P < .012$). After 6 weeks, group A and group B did not differ in their pain scores (Table 2).

The range of movement observed improved as the pain score fell. The initial median for group A was 3.6, while for group B the figures were 3.3; at this stage, the groups did not differ significantly. After 3 weeks, there was a significant difference ($P < .008$) between the groups, with the median score of group A rising to 4.1. Following the second 3-week period of active treatment, this increased to 4.8. When those in group B were given active units, they too improved significantly, with the median rising from 3.45 at 3 weeks to 4.6 ($P < .005$) at 6 weeks. After 6 weeks, group A and group B did not differ in their range of movement.

The analgesic consumption of group A and group B was quite different at the beginning of the study, with a median 5 tablet/day in group A and 2 tablet/day in group B. The analgesic consumption of the patients was computed by adding the total number of NSAIDs and other analgesics taken in the day. The reported initial difference between the groups was largely related to a preponderance of patients on short acting NSAIDs, eg, indomethacin in group A, and on longer acting NSAIDs in group B, eg, ketoprofen. Because patients were not all

TABLE 3
PATIENTS' SUBJECTIVE ASSESSMENT OF OUTCOME

| | Group A | | Group B | |
|---|---|---|---|---|
| **Week** | **3** | **6** | **3** | **6** |
| Completely well | 1 | 2 | 0 | 0 |
| Much better | 2 | 7 | 1 | 6 |
| Moderately better | 5 | 1 | 1 | 1 |
| Mildly better | 1 | 0 | 2 | 2 |
| No change | 1 | 0 | 6 | 1 |
| Mildly worse | 0 | 0 | 0 | 0 |
| Moderately worse | 0 | 0 | 0 | 0 |
| Much worse | 0 | 0 | 0 | 0 |
| Worst possible | 0 | 0 | 0 | 0 |

put on a standard analgesic combination, it was impossible to analyze the direct effect of PEMT comparing the two groups. This did not, however, preclude legitimate intra-group analysis on the effect of PEMT on analgesic consumption.

In those patients treated with PEMT for the first 3 weeks, the median fell to 4 tablets/day and again over the next 3 weeks to end up with a median of 1 tablet/day. Over both periods, the change was significant. In group B, the analgesic consumption did not change in the first (placebo) phase, but fell significantly during the active PEMT treatment ($P = .028$). After 3 weeks of PEMT, the median had fallen from 2 tablets/day to $^1/_2$ tablet/day (Table 2).

The patients' global assessment of their treatment over the two phases of this trial reflects the observation on pain and range of movement. At 3 weeks, 8 of 10 patients in the active group felt either "moderately better" or "much better," while only 2 of 10 patients in the placebo group felt that they were in these categories. At 6 weeks, all 10 patients in group A and seven of the patients in group B considered themselves to be in the "moderately better" or "much better" categories (Table 3).

There was no significant difference in battery voltage between the groups at the end of either 3-week period, indicating a similar treatment duration. Some of the patients complained of pins and needles in their neck when they took off their PEMT collars after the first three or four sessions. Patients were told to expect no sensation from any of the units. The pins and needles disappeared in all cases. No other side effects were reported. Many of the patients slept while wearing their collars and found this a convenient way to use the units for the desired treatment time.

## Discussion

Persistent neck pain is common. The etiology is usually either cervical spondylosis or a whiplash injury, though the precise pathogenesis of symptoms in an individual case may be difficult to define. Important factors in the development of pain are probably encroachment on inappropriate space and impairment of movement.[25] Compression of pain sensitive tissues by osteophytes at the posterior facet joints or the anterior joints of Von Luschke can impinge on local blood supply and/or the spinal nerve roots, which emerge close to the facet joints. Other important factors in an individual case may be a congenitally narrow spinal canal,[26] inequality of the vertebral arteries[27] or their arterial branches,[28] and nerve root sleeve fibrosis.[29] These variables may lead to a great variation in the susceptibility to ischemia at each cervical level. Cervical radiographs are of limited value because of the discordance between radiologic changes and symptoms.[30] This study attempted to evaluate a low energy, portable form of PEMT in an unselected group of patients with chronic neck pain. The lack of side effects and prolonged exposure allowed by the very low energies used, permitted the use of the units at home with minimal supervision.

Short wave diathermy is a well established form of physical therapy in which beneficial effects result from deep heating of the tissues.[30] The time needed to optimize beneficial effects is between 5 and 30 minutes.[31] Prolonged or excessively intense conventional short wave diathermy treatment may be associated with burning and localized irritation. Lenticular[32] and testicular[33] damage have been reported after careless administration of this modality. The beneficial effects claimed for short wave diathermy that might be relevant to treating patients successfully with persistent neck pain include pain relief,[34,35] an elevation of pain threshold,[36] a reduction in spindle excitability secondary to a stimulation of gamma fiber activity,[37] increased collagen extensibility in tendons because of changes in viscoelastic properties of collagen,[30,38] a reduction in muscle spasm,[39] and joint stiffness.[40]

Unfortunately, there have been few studies testing the clinical efficacy of shortwave diathermy for many of the ailments it must combat daily. Nagelschmidt's suggestion[23] that there were thermal and athermal effects associated with short wave diathermy suggests that in using a pulsed low energy form over long exposure periods, one may be maximizing an effect which is either not present or not optimal when a 30-minute treatment is given (the maximum allowed with the conventional high energy machine in everyday use). We now have proof of athermal effects for PEMT in inflammatory situations[18,19,21,22] in modulating enzyme function[41-43] and in other situations,[44] showing that without heating, electromagnetic waves have biological effects.

Wilson, using a pulsed short wave machine with a maximum power output of only 10mW (approximately six times greater than the power used in the current study), found a significant improvement in the speed of healing of ankle ligament injuries compared to

controls.[21] This suggested that pulsed low energy 27MHz waves had clinical effects even with short treatment times. A follow-up study[45] compared continuous and pulsed short wave (of the low energy type used in the previous study) in the treatment of ankle ligament injuries. The group using the pulsed form showed a significant improvement in pain at the 0.1% level compared to the continuous short wave diathermy treated group. Wagstaff et al[46] reported a significant improvement using conventional pulsed short wave in a trial comparison with continuous short wave diathermy in groups of low back pain patients. From these studies, it can be inferred that pulsed short wave diathermy at low energies is clinically effective and that, in some instances, it is more effective than conventional short wave diathermy even with short (30-minute) treatments. Pulsed electromagnetic fields have some different effects than continuous electromagnetic therapies.[47]

The precise interactions of PEMT in the form used at a tissue level in this study are not yet clear. Benthall has proposed that cellular repolarization takes place in damaged cells exposed to low energy high frequency PEMT.[48] Because the cell membrane is an excellent insulator, it is more likely that the effects of PEMT are directed at transmembrane proteins where atomic changes lead to biochemical conformation changes that activate cell signalling mechanisms and affect cellular responses.[49] At low frequency PEMT three groups of enzymes have been found sensitive to electromagnetic fields: membrane bound adenylate cyclase,[41] cyclic AMP independent protein kinase,[42] and ornithine decarboxylase.[43] Changes in the levels of these enzymes have profound effects on cellular functioning.

Very small energies are needed to cause several nonthermal effects, including cellular orientation on cells in vitro.[44] Specific forms of PEMT show narrow therapeutic "window effects" in different tissues.[50] This individualized response is probably related to cell size and intrinsic magnetic susceptibility of the cell.[51] PEMT parameters that are important in determining the cell response are frequency, rise time, pulse repetition frequency, and amplitude.[47]

In the present study, the reduction in pain and improvement in mobility are likely to have been due to an antiinflammatory prohealing effect previously described with pulsed short wave[18,19,21,45] or a facilitatory effect on nerve injury healing.[20] This study shows that even much lower energies than previously used in the form of pulsed short wave frequency have clinical effectiveness. Cameron reported the following antiinflammatory effects seen using radiofrequency in an experimental study[52]: increase in the number of white cells, histiocytes, and fibroblasts appearing in a wound, acceleration of edema and haematoma resorption, and a more organized, orderly orientation of fibrin fibers and the deposition of collagen. Raji and Bowden hypothesized that the effects they observed on nerve regeneration were due to reduction of pain and discomfort, a decrease in collagen deposition, or some primary effect on the neurons themselves.[53]

Soft cervical collars are widely used as a therapeutic modality in patients with neck ache. There is little evidence, however, that soft collars restrict movement to any appreciable extent.[54] We used a soft collar to provide some support, but mainly to allow comfortable, close access of the pulsed field to the skin surface in the present study. The duration of our study was chosen because many patients in an earlier open study appeared to benefit within 3 weeks. In the first phase, the treated group showed a significant improvement compared to the placebo group. When the patients who had the placebo therapy in phase one were given active units in phase two, they also responded. It is unlikely, therefore, that spontaneous improvement or use of a soft collar accounts for the symptomatic improvement observed. It appears that PEMT would have speeded the resolution of symptoms.

As there was no significant difference between the two groups at the end of 6 weeks, it can be inferred that most of the benefit was achieved over the first 3 weeks of active treatment. Patients had no difficulty in using the portable PEMT units without supervision at home. Therefore, clinic visits and visits to physiotherapy are not necessary during treatment with PEMT. During active treatment, the four parameters chosen—visual analogue pain score, range of movement, pill count, and subjective assessment—all improved significantly. The optimal treatment duration and the minimum treatment duration effective for the type of PEMT described is as yet unknown. Chard et al reports that 8-hour per day therapy shows a significant advantage in terms of early symptomatic relief of patients with rotator cuff tendonitis compared to 2 hours of medium power low frequency PEMT.[55] By 1 year, both groups treated for 8 weeks noted a similar improvement in symptoms and function. Further studies on low energy high frequency PEMT are indicated to clarify what is optimal treatment.

Seventy-five percent of patients graded their response as "moderately better" or "much better" on a subjective evaluation at the end of the study. The beneficial effects in terms of reducing pain and improving movement were seen within 3 weeks of commencing treatment. Many patients gained little benefit in the initial week, but by 2 weeks had noted a definite improvement. We conclude that the significant patient improvement, as judged by both patient and clinician, implies a role for PEMT in the treatment of persistent neck pain.

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