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LOW ENERGY HIGH FREQUENCY PULSED ELECTROMAGNETIC THERAPY FOR ACUTE WHIPLASH INJURIES[1]

A Double Blind Randomized Controlled Study

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ABSTRACT. The standard treatment of acute whiplash injuries (soft collar and analgesia) is frequently unsuccessful. Pulsed electromagnetic therapy PEMT (as pulsed 27 MHz) has been shown to have pro-healing and anti-inflammatory effects. This study examines the effect of PEMT on the acute whiplash syndrome. One half of the 40 patients entering the study received active PEMT collars: the other half facsimile (placebo). All patients were given instructions to wear the collar for eight hours a day at home and advised to mobilise their necks. At 2 and 4 weeks the actively treated group had significantly improved ($p<0.05$) in terms of pain (visual analogue scale). By chance movement scores for the PEMT group were significantly worse at entry to the study than the control group ($p<0.05$). At 12 weeks they had become significantly better ($p<0.05$). PEMT as described is safe for domiciliary use and this study suggests that PEMT has a beneficial effect in the management of the acute whiplash injury.

Key words: short wave diathermy, neck pain, neck sprain, whiplash, electromagnetic field.

Since the Second World War there has been a dramatic increase in the number of motor car accidents resulting frequently in neck injuries and an associated whiplash syndrome (1). The syndrome's perception for many people is that of a neurotic or even malingering guise, by which many people involved in vehicular accidents fraudulently gain compensation after a trivial injury. The literature does not support such a view, as will be later elucidated.

While the persistence of neck pain suggests we are not efficiently treating the cervical component of the whiplash injury, there have been surprisingly few therapeutic studies comparing treatments for the patients with acute whiplash syndrome. The standard treatment for acute whiplash injuries has been immobilisation in a soft cervical collar combined with adequate analgesics (2, 3). Early active mobilisation has only recently been shown to be more effective than the standard treatment (4). Because of the cost involved in providing such an immediate service, this has only become available in certain centres (5). McKinney's recent report (6) shows no difference in early management outcome (using pain and range of motion as the important outcome parameters) between outpatient physiotherapy and a structured verbal and written mobilisation instruction programme geared to facilitating self-mobilisation.

Over the last thirty years increased attention has focussed on the use of electrical signalling to stimulate tissue healing especially in cases where conventional therapy is ineffective. This has resulted from the seminal observations of Becker (7), Bassett et al. (8) and Fukada & Yasuda (9) that bioelectrical fields are associated with limb regeneration and bone dynamics. These studies suggested that imposed fields could selectively trigger desirable biomechanical events if the appropriate field parameters were used. Pulsed electromagnetic therapy (PEMT) has been shown to accelerate fracture healing in refractory cases (10, 11) and used to treat failed joint arthrodesis (12) and avascular necrosis (13). Low frequency (40–70 Hertz) medium power PEMT has been used in these trials. Higher frequency PEMT devices have been reported to accelerate wound healing (14) dental alveolar healing (15) and nerve regeneration (16, 17). Symptomatic relief and accelerated healing have also been reported in studies of patients with ankle ligament injuries

[1]An abbreviated form of this study has been presented at the British Society for Rheumatology meeting in Birmingham, July 1988, at the American College for Rheumatology meeting in Cincinatti, June 1989, and at the Bioelectromagnetic Society meeting in Tucson, June 1989.

(18) and rotator cuff tendonitis (19). We have recently reported that low energy high frequency PEMT improves pain and increases range of motion in patients with persistent neck pain (20). Low power PEMT would deliver approximately 1.5 milliWatt/cm^2 while medium power would deliver approximately 0.5 Watt/cm^2 at the skin surface. Nagelschmidt in 1940 proposed in relation to the therapeutic effectiveness of short wave diathermy "there must be some other effect, not as yet realised to account for the phenomena which could not be reasonably attributed to heat alone (21)". In this study we chose low power pulsed short wave (approximately 27 MHz) because of its safety over prolonged periods (22) allowing a safe eight hour/day minimum treatment duration, with minimal inconvenience for the patient treated in their own home. To assess the impact of treatment in acute whiplash injuries using low energy high frequency PEMT we conducted a double-blind randomised controlled trial in a group of patients presenting with acute whiplash injuries resulting from rear end motor vehicle accidents.

PATIENTS AND METHODS

The Accident and Emergency (A & E) Department of Mater Misericordiae Hospital Dublin serves a population of 500 000 providing a 24-hour emergency service in rotation with two other major hospitals. Between September and December 1987 all patients over 18 years who presented with acute "whiplash" injuries (injuries of the cervical spine resulting from rear end collisions), were considered potential candidates for a randomized trial of PEMT. The study was approved by the hospital Ethical Committee. Initial assessment of potential study subjects was by history taking, physical examination and radiographs of the cervical spine (A/P and Lateral). Persons who presented to the A & E Department more than 72 hours after the injury or who had any active inflammatory, infective, neoplastic, or metabolic bone disease involving the cervical spine were not included in the trial. In addition anyone who had sustained a cervical fracture, a head injury with loss of consciousness or who had imparied reflexes indicative of a cervical root lesion was excluded. The trial purpose and design was explained to suitable subjects and their consent to participate was sought. A total of 40 persons were enrolled in the trial. The patient data is presented in Table I. Eight patients in each group showed either reduction in disc height, osteophytes, facet joint hypertrophy and either flattening or reversal of the normal cervical lordotic curve. There was no significant difference between the treatment and control groups with respect to age, sex distribution or previous whiplash injury.

Table I. *Demographic and clinical data*

	Group A (PEMT) ($N=20$)	Group B (Soft collar) ($N=20$)	Sinificance level
Age (yrs)			
Median	31	31	NS
Range	22–60	17–52	
Gender M/F	2:1	3:1	NS
Previous whiplash	4 (20%)	1 (5%)	NS*
Physiotherapy at 4/52	9 (45%)	12 (60%)	NS
Possible litigation	14 (70%)	13 (65%)	NS

* Fisher's exact test.

Type of PEMT unit

The "treatment" units were designed as active PEMT units and dummy (facsimile) units, twenty of each type. An active PEMT unit consisted of a soft collar into which a flexible miniaturized short wave diathermy generator, weighing approximately 100 grams was incorporated. The generator produces a pulsed magnetic field in the treatment area with mean power of 1.5 milliWatts/cm^2 at the patient's surface. The nominal frequency of the unit was 27 MHz, with a pulse burst width of 60 microseconds and a repetition frequency of 450 per second. Each unit was controlled by an On/Off switch. An indicator light confirmed that the system was operational. The power source for the unit was two nine volt batteries which were replaced at four weeks.

The facsimile unit was also a soft collar into which a generator of equal weight was incorporated but did not produce PEMT waves. The facsimile unit also had an On/Off switch and an indicator ligth which was battery operated. The units were supplied, each bearing an identity number, by H and K Electronics. The status of each unit (i.e. whether active or facsimile) was known only to the agent for the manufacturers. There is no perceptible sensation associated with the use of low energy high frequency PEMT as described nor does the collar with the unit enclosed make any perceptible noise.

Study design

As patients were enrolled in the study they were randomly assigned a collar, the status of which was unknown to either the patient or the principal investigators (D. F.-N. and K. M.). Patients were advised to wear their collar for eight hours per day for the duration of the study (12 weeks). Patients were also prescribed the same anti-inflammatory analgesics (mefenamic acid) and asked to record their daily consumption of this medication, reducing them if they no longer needed them. Patients were advised to mobilise their necks hourly doing each of the six cervical movements five times each within their pain-free range. Patients were referred for physitotherapy treatment if they were unhappy with their progress at four weeks. The treatment was given twice weekly for six weeks and was tailored to the individual's needs. Typical management included hot pack, pulsed short wave diathermy (SWD), ultrasound and active repetitive movements.

Assessment

Patients were assessed at entry to the trial and at 2, 4, and 12 weeks. At each assessment the endpoints of interest were level of pain, range of neck movement and subjective assessment

Table II. *VAS Pain, movement and analgesic consumption*

Time	Group A (Active)		Group B (Control)		Significance level between group comparison
A. VAS pain scores median					
0	6.75	*$p<0.05$	6.25	*NS	NS
2/52	3.75	*NS	6.00	*NS	$p<0.05$
4/52	2.5	*NS	5.00	*$p<0.05$	$p<0.05$
12/52	1.5		2.25		NS
B. Movement scores median					
0	2.83	*NS	3.66	*NS	$p<0.05$
2/52	3.0	*$p<0.02$	3.50	*$p<0.01$	NS
4/52	4.0	*NS	3.33	*$p<0.01$	NS
12/52	4.50		4.00		$p<0.05$
C. Number of analgesics median					
0	5.0	*NS	6.0	*NS	NS
2/52	3.5	*$p<0.01$	6.0	*NS	$p<0.05$
4/52	2.5	*$p<0.01$	5.0	*$p<0.01$	$p<0.05$
12/52	0.0		1.5		$p<0.05$

* Within group comparison.

of progress. Pain was assessed by means of a visual analogue pain scale (VAS) (10 cm horizontal line with "no pain" and "worst possible pain" marked at either end of the line), and by analgesic consumption. Cervical range of movements (ROM) were graded as full, two thirds normal, one third normal or absent. Thus, a patient could 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 each review patients were asked to make a global assessment of their progress over the previous three 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. If at four weeks patients were dissatisfied with the progress they had made over the initial four weeks they were referred for mobilizing physiotherapy. The number code designating active and facsimile units was broken only upon completion of the 12 week assessment of all patients.

Statistical methods

Demographic and clinical features of Group A and Group B were compared using the Wilcoxon ranked sum test, Chi squared test and Fisher's exact probability test as appropriate. Changes in pain and movement scores *within* each group were assessed using the Wilcoxon signed rank sum test. Statistical significance implies $p<0.05$ unless otherwise stated.

RESULTS

Patients were assessed at the initial visit in the A & E department at a median of 24 hours (range 2–60) after their whiplash injury had been sustained. The level of compliance among trial participants was remarkably high. All patients who entered the study attended for assessment at the designated times and completed the study. In addition, each patient wore the collar for the recommended period of time and kept a log of his/her analgesic consumption.

There was no difference in pain score at entry to the trial between the groups. The median pain scores of both groups are presented in Table II and graphically in Fig. 1. At two weeks and four weeks, the treatment group had significantly less pain than the control group. Of interest was the fact that in both active and placebo groups the VAS median pain was initially higher for females than for males, 7.75 compared to 6.5 (active) and 8.0 compared to 6.5 (passive). While this trend was maintained at 4 weeks (i.e. female scores higher than male scores) in both active and placebo groups, by 12 weeks it was only true for the placebo group. At no time was the difference noted statistically significant; however the number of females in each group was small (Table I). At 4 weeks 9 patients in the treatment group and 12 patients in the control group were referred for mobilizing physiotherapy. At 12 weeks the median pain scores were 1.5 and 2.75 respectively which difference was not statistically significant. Within group statistical analysis

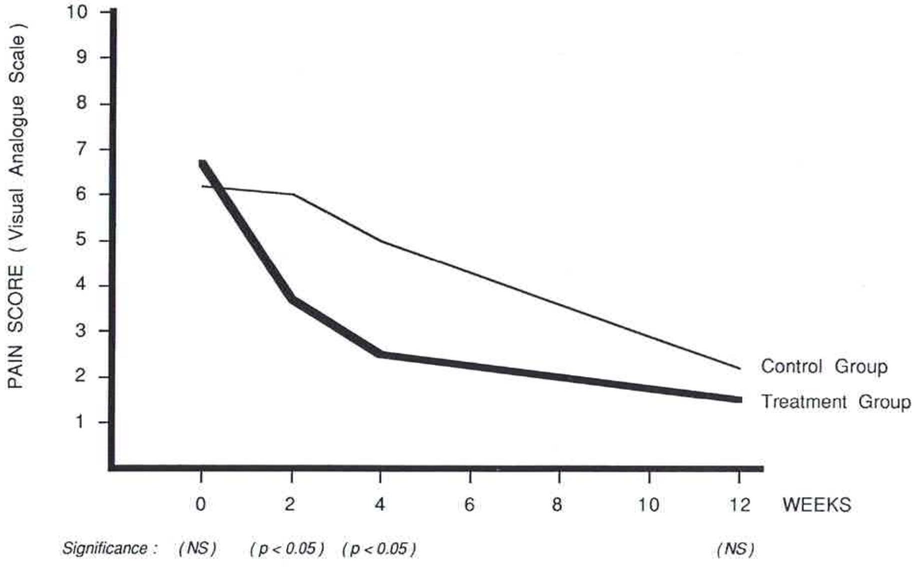

Fig. 1. Median pain scores in treatment and control groups at baseline, and after 2. 4 and 12 weeks.

showed a significant improvement in pain by two weeks and thereafter at four and twelve weeks in the actively treated group and only by twelve weeks in the control group.

Range of movement (ROM) scores, which improved as pain scores fell, are presented graphically in Fig. 2. While by chance alone the ROM scores of the treatment group were significantly worse than the ROM scores of the control group at entry to the trial ($p<0.05$), they were significantly better at the end of the trial ($p<0.05$). To examine this finding further, we looked at the outcome for individuals within each group. In the treatment group 19/20 (95%) showed an improved ROM at 12 weeks while in 1 person the ROM was unchanged. In the control group, however, 10/20 (50%) had a better ROM, in 6/20 (30%) the ROM was unchanged and 4 patients (20%) had a reduced ROM at 12 weeks compared with entry ROM. Comparing median ROM scores within (rather than between) each group there was no significant improvement from entry to 12 weeks in the control group. The treatment group showed a highly significant ($p<0.001$) improvement, however (Wilcoxon signed rank test).

Patients in the control group were taking a median of six tablets on their first visit and five tablets a day by four weeks as compared to five tablets initially falling to three and a half in the actively treated group. The actively treated groups reduction was statistically significant when compared to the control groups at the two and four weeks assessment. By twelve weeks the groups were again comparable in terms of analgesic consumption (Table II). The patients global assessment of their treatment reflected the changes in pain and range of movement. At four weeks 17/20 (85%) in the actively treated group felt either "moderately better" or "much better" while only 7/20 (35%) in the control group placed themselves in these categories, which was highly statistically significant ($p<0.001$). At 12 weeks the proportions improved (in the "moderately better" or "much better" categories) were 85% in the actively treated group and 60% in Group B (Table III), respectively.

DISCUSSION

Hyperextension hyperflexion injuries of the neck were first described with the popularisation of train travel and consequently train accidents in the latter half of the 19th century (23). Crowe in 1928 introduced the term "whiplash" to describe a syndrome resultant from rear-end motor vehicle accidents, in which as a result of sudden acceleration and deceleration of the neck with forced hyperextension likely to be the more damaging movement, damage is done to the underlying structures (24). In common usage the term has come to mean the syndrome of neck pain and other features resultant from vehicle impacts in

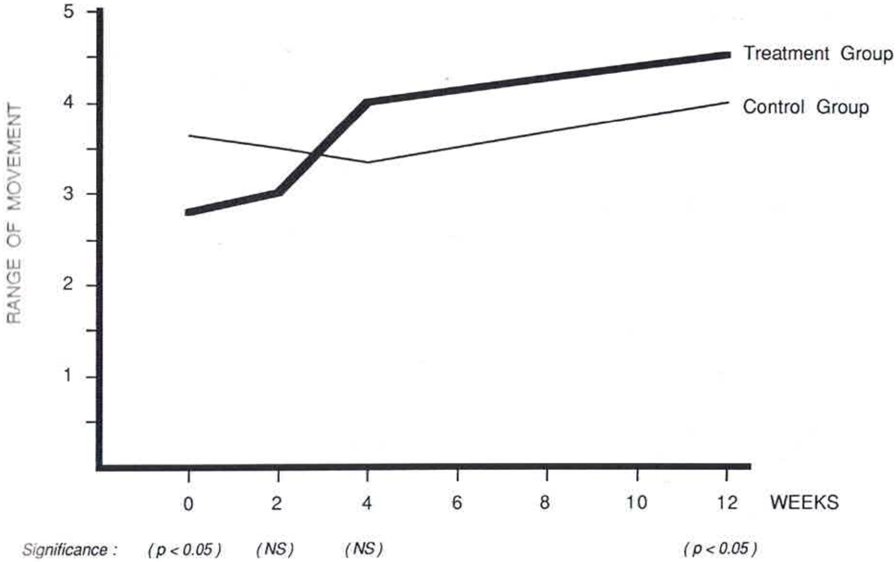

Fig. 2. Median range of movement in treatment and control groups at baseline, and after 2, 4 and 12 weeks.

any direction rear front or side. As the whiplash injury is perceived by many to be no more than a relatively trivial soft tissue injury frequently associated with compensation claims the term itself is considered by many to be emotive and unhelpful. Nonetheless it has merit in that it emphasizes the fact that while we understand the mechanism we are unsure of the pathology involved. Animal studies (25, 26) and studies using brave volunteers (27) have established that the forces generated even in low velocity impacts are considerable, e.g. in a 10 mph rear-end collision

Table III. *The patients' subjective assessment of outcome*

	Group A (PEMT)		Group B (Soft collar)	
Week ...	4	12	4	12
Completely well	1	4	0	2
Much better	8	12	6	8
Moderately better	8	1	1	2
Slightly better	2	1	6	5
No change	1	1	3	2
Slightly worse	0	1	2	1
Moderately worse	0	0	0	0
Much worse	0	0	1	0
Worst possible	0	0	1	0

Between group comparison 4/52 $p=0.001$.

the force at the cervical region would be 9 g (27). Hohl has documented that muscle ligament and nerve injuries can occur in his animal whiplash model (28).

There are great variations in the prevalence of persistent neck pain arising from rear-end motor accidents ranging from 75% (29) to 25% (30) of symptomatic patients at six months in different studies. Persistent neck ache is one of the most frequently disabling features of the whiplash syndrome (2) causing sick leave in up to 39% of patients (31), permanent medical disability in up to 9.6% of patients (29) and interference with daily living in 59% of patients (32). Because of the frequent concomitant claim for compensation the authenticity of symptoms has been queried by many authors (33, 34).

If a motive (financial gain) rather than an organic lesion was the ultimate basis for the persistence of neck pain after whiplash injuries, then settlement of such compensation claims should allow the neck pain to resolve with litigation settlement. Gotten (35) found that 46% of whiplash patients reviewed 1–26 months after compensation case settlement still had symptoms (12% were still severely incapacitated by their injuries). Another report gives a 45% figure for neck symptoms two years after settlement (1) while Hohl found 43% had some neck pain five years after settlement (3). It is easy to imagine how the added worry of impending litigation may have a tendency to amplify and perpetrate symptoms. Analyzing the results of these studies performed post litigation settlement suggest that a sizeable proportion of patients continue to experience neck pain thereafter.

The persistence of neck pain in many different cultures and in cases where there was no litigation involved corroborate the case for an underlying organic basis for the symptoms (23). The prolonged duration of symptoms in comparison to the expected normal recovery period for a soft tissue injury (1) suggests that the injury causing persistent symptoms is not the traditionally accepted whiplash injury, a grade I or II ligamentous injury. Magnetic resonance imaging (MRI) can demonstrate soft tissue cervical structures in great detail (36). An MRI study to establish which tissues are damaged and the extent of such injuries would help our understanding of the whiplash injury.

A previous study showed that low energy high frequency PEMT can benefit patients with persistent neck pain (20). The ease of use and lack of side-effects allowed a safe home treatment, while the low energies allowed a safe eight hour per day treatment. No side-effects were reported in that study or in the present study using the same form of PEMT other than pins and needles on taking off the collar in the early stages. This resolved in all cases. This study's design was based on the previous study which showed that this form of PEMT reduces pain within three weeks in patients with persistent neck pain.

The most immediate improvement seen in the present study was in terms of pain reduction in the PEMT treated group with a significant reduction in pain VAS seen at 2 weeks and reflected in a significant reduction in analgesic consumption and an improvement in the subjective assessment of progress at the monthly follow-up visit. The changes in range of neck movement were more gradual. While by chance alone the treatment group had a statistically significant stiffer neck at the initial observation by three months the treatment group had a more mobile neck. It would appear that pain relief occurs more quickly in patients with whiplash treated by PEMT than does an improvement in ROM. The subjective assessment of progress mirrored the improvements in the other parameters with a clear benefit in outcome greater than placebo perceived by the actively treated group at four weeks.

At four weeks patients who were not happy with their progress were referred for a physiotherapy regimen. As earlier described 45% of the actively treated group and 60% of the placebo treated group took this option. These figures suggest that most of the patients still perceived themselves to be having some trouble at four weeks. It is noteworthy that the majority of patients (70% in Group A and 65% in Group B) were considering seeking financial compensation when asked about this at twelve weeks. More patients in the actively treated group felt themselves improved compared to the placebo group (85% vs. 60%) at 12 weeks. Their improvement reflects the natural history of recovery as well as the effects of the various treatments employed, analgesics, home-exercises, physiotherapy and PEMT collar/soft collar. The gradual improvement in ROM of the actively treated group suggests that the beneficial effects of PEMT in achieving this depend on pain reduction or else that a longer duration of PEMT exposure is needed to achieve different clinical effects.

In the present study low energy pulsed 27 MHz was used. 27 MHz is the frequency commonly used in SWD machines which are a well accepted form of physical therapy (37), whose beneficial effects are generally accepted to be related to deep heating of the tissues, though this has been disputed (21, 38). Optimal treatment time for SWD is between five and thirty minutes (39). Longer treatments can result in significant complications in addition to burning and localized irritation (40, 41).

In the context of successfully treating whiplash patients the beneficial effects of conventional high energy SWD reported that might be important are: pain relief (42), a reduction in muscle spasm (43), an elevation of pain threshold (44), a reduction in spindle excitability (45) and joint stiffness (46). Notwithstanding the widespread use of SWD there are a paucity of controlled studies examining the benefits of SWD in the treatment of the various specific musculo-skeletal conditions including whiplash. The seminal observation of Nagelschmidt (21) that there were athermal beneficial effects of SWD suggest that a longer treatment time might maximize such effects. Recent observations have demonstrated athermal effects of PEMT in inflammatory conditions (14, 15, 18, 19), in modulating enzyme functions (4, 7, 48, 49), and in producing effects as cellular orientation (50). These effects corroborate the initial report and testify to the biological athermal effects of PEMT.

Wilson (18) has demonstrated that pulsed SWD (at an energy level approximately six times greater than the present study) produces a significant improvement in ankle ligament injury repair. Pulsed SWD was shown to be significantly more effective than continuous SWD in a subsequent study of ankle ligament injuries (51) while Wagstaff (52) found a similar result in treating low back pain. The energies used by Wilson & Wagstaff in their pulsed SWD studies are comparable to the present study and have achieved both analgesic and anti-inflammatory effects. Their superior results achieved by pulsing SWD thus using lower amounts of energy than used in conventional SWD suggests that the total energy transfer does not determine the degree of beneficial effects seen and that parameters as the pattern and pulse repetition frequency may be just as important as the amplitude of the PEMT associated field, provided one is above a critical threshold level. How such PEMT parameters modulate overall effectiveness has yet to be determined. These studies show that low energy pulsed SWD is clinically effective and sometimes more effective than continuous SWD even with short (30 min maximum) treatments. Pulsing electromagnetic fields have some different biological effects than using continuous therapy (53, 54).

The precise interactions of pulsed SWD (PEMT) in the form used in this study at a tissue level are not yet known. The very low energies involved imply a co-operative signalling mechanism at the cell membrane surface (55) resulting in electronconformational alteration in specific proteins (56). Such a phenomenon (a significant change in enzyme function presumably related to a change in conformational shape of the enzyme) has been reported to occur for three important enzymes membrane bound adenylate cyclase (48) cyclic adenylenemonophosphate independent protein kinase (47) and ornithine decarboxylase (49) after exposure to specific PEMT waveforms.

Among PEMT parameters that are important in determining the cell response are carrier frequency, rise time, pulse repetition frequency and amplitude (50). Specific forms of PEMT show narrow therapeutic "window effects" in different tissues (57). The present study shows that lower energy pulsed SWD used over a longer time period has clinical effectiveness. In broad outline the beneficial effects seen in this study in reducing pain and improving mobility are likely to be due to similar pro-healing and anti-inflammatory effects previously reported (14, 15, 18, 19). The facilitatory effect on nerve injury healing is also possibly important (16, 17).

The management of acute whiplash injuries is a problem because of the ineffective standard treatment (2) (soft collar and analgesia). There is little evidence that soft collars restrict neck movement to a significant extent (58). The present study sought to combine the passive support of a soft collar with an active treatment modality. The comfortable apposition of the collar surface to the neck allowed close access of the pulse field to the cervical structures. The duration of this study was chosen because in an earlier study of persistent neck pain many patients significantly improved within three weeks (20). 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. Mealy has shown that mobilisation is effective in the treatment of acute whiplash injuries (4) while McKinney (6) reported that there was no significant difference in efficacy comparing outpatient physiotherapy and a structured verbal and written mobilisation programme geared to facilitating self-mobilisation in the early management of whiplash. In the present study all patients were instructed to self-mobilise as quickly and as completely as their pain allowed. It would appear prudent that a self-mobilisation instruction programme should now be included as part of the management regime for all whiplash patients.

This study and our previous study (20) suggest that low energy high frequency PEMT administered for eight hours a day is effective in acute and persistent neck ache. Chard has reported that eight hours/day treatment with a medium power low frequency PEMT gave significantly better acute symptomatic relief in patients with rotator cuff tendonitis than two hours/day treatment (59). Further studies to define the minimum effective duration of treatment and what constitutes optimal therapy are indicated for whiplash and other treatment groups. In conclusion the significant patient improvement as judged by both patient in terms of pain and subjective assessment and clinician in terms of ROM, strongly suggests that PEMT has a beneficial effect in the early management of the acute whiplash injury.

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