Effect of pulsed magnetic field therapy on pain reported by human volunteers in a laboratory model of acute pain†

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Background. Pulsed magnetic field therapy (PMFT) is a non-invasive, simple technique used extensively for the treatment of muscle pain. However, evidence to support its use from well-designed, clinical, or experimental studies is sparse.

Methods. We have utilized an acute pain model to perform a randomized, double-blinded, placebo-controlled, crossover-study on 10 male (18–40 yr) volunteers. Pain was elicited by infusion of hypertonic saline 5% into the brachioradialis muscle of the non-dominant arm on two occasions, at least 1 week apart. Subjects received active or sham PMFT for 30 min in a randomized order delivered by two identical, commercially available machines (PulsePack 6000, Quantum Techniks). The active machine delivered a M-wave magnetic pulse (1.25 Hz, 3 ms width, 600 Gauss); the sham device was deactivated and delivered no magnetic energy. Pain was assessed at 15-s intervals, and area under the visual analogue score (VAS) pain curve (AUCp) was calculated using the trapezoid method.

Results. There were no significant differences in mean VAS pain scores between the two machines at any time. In addition, there were no significant differences with respect to mean (SEM) maximum pain score [sham 60 (8), active 63 (9) mm; P = 0.66, 95% CI −18 to 12 mm] or AUCp [sham 463 (50), active 499 (90); P = 0.64, 95% CI −201 to 129].

Conclusions. We conclude that, using the electromagnetic characteristics of the machine in this study, the PMFT had no effect on pain in our experimental model. More work is required to provide an evidence base in support of the use of this technique for pain.

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Magnetic therapy is a non-invasive, simple, and safe technique, often administered over the site of a painful injury or inflammation. It has been used for this indication for centuries, and claims of analgesic efficacy have been made.¹² Both static and pulsed magnetic fields have been used. The major difference between these is that the pulsed magnetic fields induce small electrical (Faraday) currents in the tissues because of the constantly changing magnetic flux.³ It has been postulated that these currents are the mechanism underlying the claimed analgesia associated with pulsed magnetic field therapy (PMFT). It has also been suggested that they cause vasodilatation, modification of the inflammatory process, reduction of oedema, and enhanced tissue repair.¹³⁴ Others have suggested a direct effect on nerve transmission.⁵

Many manufacturers of medical equipment market a PMFT machine, and they are used extensively worldwide. Systematic reviews have found some evidence for pain relief in the treatment of osteoarthritis of the knee and

†Data from this study were presented at the Anaesthetic Research Society meeting, Loughborough, November 2005.
cervical spine\textsuperscript{6–9} however, data in arthritis of the shoulder are inconsistent\textsuperscript{10}.

Most studies have examined the effect of a course of PMFT treatment on the chronic pattern of musculoskeletal pain in specific pathological diseases rather than an immediate analgesic effect in controlled experimental conditions. There are several conventionally accepted ways of provoking muscular pain in human studies: i.m. electrical stimulation\textsuperscript{11}, ischaemia and exercise\textsuperscript{12,13} and i.m. injection of irritant substances, such as hypertonic saline.\textsuperscript{14–17} The hypertonic saline method has gained widespread acceptance as the quality of induced pain is similar to clinical muscle pain, that is relatively diffuse and cramp-like.

Therefore, in order to elucidate the immediate analgesic effect of PMFT, we have performed a prospective, randomized, double-blinded, crossover, and placebo-controlled study using a recognized acute muscle pain model.

Methods

Ten healthy male volunteers aged 18–40 yr were studied. We controlled for age and sex because both these characteristics have been shown to affect pain perception.\textsuperscript{18} The study was approved by the local research ethics committee. A single investigator (MIF) provided potential volunteers with a verbal explanation of the trial and the physical and biological properties of PMFT. Written, informed consent included a description of the experiment, goals, protocol, and potential problems. After a 24-h period of consideration, the volunteers were contacted by the investigator and asked if they wished to take part in the trial. A study consent form was then signed.

Exclusion criteria for the study included: skin lesions or an open wound on the area of proposed magnet placement; generalized or local skin hypersensitivity; use of regular medications; and a history (within 6 months) of musculoskeletal pain, that is relatively diffuse and cramp-like.

To elicit pain, we infused saline 5% into the brachioradialis muscle of the non-dominant arm utilizing a technique modified from that described by Graven-Nielsen and colleagues.\textsuperscript{17} The skin was anaesthetized with 0.1 ml lidocaine 1% before the insertion of a 27-G needle into the muscle (~20-mm deep). When the subject reported no pain after the insertion of the needle, saline 5% was infused from a 20-ml syringe for 10 min (18 ml h\textsuperscript{-1} for 5 min, then 36 ml h\textsuperscript{-1}; total 4.5 ml) utilizing a syringe pump (IVAC P, model 3000).

Pain was assessed at 15-s intervals using a validated electronic visual analogue scale (VAS) device.\textsuperscript{19} Subjects were asked to rate their pain by moving a handle over the scale. The left-hand side of the scale (0 mm) was annotated ‘no pain’ and the right-hand side (100 mm) ‘worst imaginable pain’. Data were collected from the time when the infusion was started to the time when pain was rated as zero. Data were then downloaded from the device to a PC for subsequent analysis.

To investigate the effect of PMFT, we used a therapeutic electromagnetic field system (PulsePack 6000) that uses a proprietary signal designed by Quantum Techniks Ltd, UK. This commercially available machine has six circular heads (diameter 10 mm) delivering a pulsating M-wave (pulse width 3 ms, frequency 1.25 Hz, field density 600 Gauss). The PMFT heads were attached using hypo-allergic, double-sided adhesive pads, and forming a ring around the injection site. This position maximizes the strength of the pulsed magnetic field around the site of the irritant infusion and subsequent pain. The electrodes were sited in the same position for every experiment.

Subjects attended on two occasions at least 1 week apart; they were randomly allocated to receive therapy from an active or sham machine. The investigator and volunteer were blinded to the nature of the machine. The machines were marked A or B, but were otherwise externally identical; the sham machine was adjusted internally so that it did not deliver a magnetic field. The PMFT device was switched on 5 min before the start of the saline 5% infusion and continued for 30 min. Pain scores were recorded until the subject experienced no pain. In every case, this happened within 10 min of stopping the infusion. Subjects were aware that the infusion could be stopped on request at any time.

Power and statistical analysis

Previous studies utilizing a hypertonic saline infusion have demonstrated a large between-subject variation in pain scores; however, within-subject pain scores are consistent and reproducible.\textsuperscript{15} Using data from the previous work on this experimental model\textsuperscript{17} and assuming an α-error of 0.05 and β-error of 0.2, we calculated that nine volunteers would be required to detect a difference of at least 20 mm in maximum pain scores on the VAS scale between the treatments in this crossover-design.

The area under the VAS pain score curve (AUC\textsubscript{p}) was calculated for each experiment using the trapezoidal method. After confirming that the data were normally distributed (Kolmogorov–Smirnov test), individual and maximum VAS scores, and AUC\textsubscript{p} were compared using a paired t-test and paired ANOVA for repeated measures, as appropriate (SPSS for windows Version 11.5).

Results

A total of 13 volunteers were recruited. Three were withdrawn from the study on the first visit because of equipment failure (n=1) and persistent pain after insertion of the needle before saline infusion (n=2). Therefore, 10 subjects completed both arms of the study.

There were no significant differences at any time in the mean VAS pain scores during active and sham therapy (Fig. 1). Mean (SEM) AUC\textsubscript{p} was 499 (90) during active treatment compared with 463 (50) during sham treatment (no significant difference). Also, there was no significant
difference in the maximum VAS pain scores between treatments (Table 1). The 95% confidence intervals of the difference ($-18$ to $12$ mm) of the maximum pain scores confirm the validity of our power calculation and indicate that it is unlikely that we have failed to detect a clinically significant difference in this measurement.

**Discussion**

Magnetic devices are widely used as a complementary therapy for many medical conditions. They are safe, simple, non-invasive, and can be used in out-patients or at home. The sale of devices providing static magnet fields (e.g. bracelets, insoles, wristbands, braces, pillows, mattresses) generates a business worth more than 1 billion dollars worldwide every year. The lack of evidence supporting the use of static magnetic fields has been highlighted in two recent editorials. One of these editorials accompanied the publication of a well-designed, randomized, double-blinded trial, which demonstrated that static magnetic therapy had no effect on morphine requirement or pain scores in patients after abdominal surgery when applied to the wound.

However, we have investigated pulsed (not static) magnetic fields that have been shown to induce Faraday currents and measurable effects on biological systems. Proponents of PMFT have suggested that its efficacy is the result of modified pain transmission, reduced inflammation, and enhanced tissue repair. However, while there is evidence for effects on inflammation, circulation, soft tissue repair, and osteogenesis in unhealed fractures, there are few data on analgesic effects.

In the present study, we have been unable to demonstrate an effect on peripheral pain sensation in an acute muscle pain model, perhaps suggesting that this is not an important mode of action of PMFT. In contrast, two previous studies investigating the effect of PMFT on clinical muscular pain in humans have demonstrated an analgesic effect, even after only one treatment. Pujol and colleagues and Smania and colleagues used the same technique of magnetic stimulation using a 20 Hz pulse of PMFT of variable but high intensity (up to 4000 Gauss). However, the studies were not double-blinded, the control group were exposed to a deactivated ultrasound machine and patients reported that the PMFT probe increased in temperature during active therapy.

In contrast, decreased nociceptive thresholds have been demonstrated in animals but the duration of the exposure was considerably longer than used clinically and the whole animal was exposed to the field. Paradoxically, analgesic effects have been reported in animals where lower amplitude exposure was used. This may suggest that the analgesic response is dependent on the characteristics of the PMFT.

The experimental technique used in this study is well established and recognized as a good model of clinical muscle pain. Pain is induced by the direct effect of the increased i.m. concentration of sodium ions, the depolarizing effect on excitable membranes, and generation of action potentials. It has been suggested that PMFT reduces the permeability of cell membranes and therefore the number of action potentials. However, there is no experimental evidence for this.

PMFT is unlikely to affect conductivity in the pain pathways. It has been estimated that the field required to produce a 10% reduction in nerve conductivity is $\sim 24$ T (240 000 Gauss). Magnets used for the treatment of pain produce fields of 300–5000 Gauss. There have been no reports of analgesic or hyperalgesic effects in humans during exposure to magnetic fields of up to 2 T. Smania and colleagues suggested that the mechanism was similar to that of transcutaneous electrical nerve stimulation (TENS); however, this is unlikely as no local sensation is experienced and there is no overt muscular response to PMFT.

Available PMFT devices utilize widely different frequencies, field strength, and pulse widths; there are few data informing the choice of these parameters. However, it is likely that tissue response is affected by frequency,

### Table 1 Mean (SEM) VASmax and AUCp (no significant differences)

<table>
<thead>
<tr>
<th></th>
<th>Control Mean (SD, SEM)</th>
<th>Active Mean (SD, SEM)</th>
<th>P-value</th>
<th>95% CI difference (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VASmax (mm)</td>
<td>60 (11, 8)</td>
<td>63 (28, 9)</td>
<td>0.66</td>
<td>$-18$ to $12$</td>
</tr>
<tr>
<td>AUCp</td>
<td>463 (158, 50)</td>
<td>499 (285, 90)</td>
<td>0.64</td>
<td>$-201$ to $129$</td>
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field strength, and pulse width, and this may explain the variable findings in the literature. There is a clear need for the methodical investigation of these parameters before we can be certain of the value of PMFT in clinical practice. The technique used in our study offers one method of approaching this task.

Our study has several limitations. We have focused on pain scores; we did not investigate other potentially important clinical effects of PMFT. The number of volunteers was small but a robust power calculation, confirmed by confidence intervals of the study data, showed that it was unlikely that we were missing a clinically important difference in pain scores. We applied the magnetic field for less time when compared with other studies. However, the duration of the application was that recommended by the manufacturer and is in common clinical use. Finally, we did not investigate the effect of different magnetic parameters.

In conclusion, we were unable to demonstrate an analgesic effect of PMFT in our study. Further work is required to elucidate the effects of different field strengths, pulse widths, and frequencies.

References

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