Electromagnetic therapy for treating venous leg ulcers
(Review)

Ravaghi H, Flemming K, Cullum NA, Olyaee Manesh A

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Electromagnetic therapy for treating venous leg ulcers (Review)

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[Intervention Review]

Electromagnetic therapy for treating venous leg ulcers

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ABSTRACT

Background
Leg ulceration is a common, chronic, recurring condition. The estimated prevalence of leg ulcers in the UK population is 1.5 to 3 per 1000. Venous ulcers (also called stasis, or varicose ulcers) comprise 80 to 85% of all leg ulcers. Electromagnetic therapy is sometimes used as a treatment to assist the healing of chronic wounds such as venous leg ulcers.

Objectives
To assess the effects of electromagnetic therapy on the healing of venous leg ulcers.

Search strategy
For this first review update, we searched the Cochrane Wounds Group Specialised Register (last searched October 2005); CENTRAL (The Cochrane Library 2005, Issue 4); MEDLINE (1966 to October 2005); EMBASE (1980 to October 2005); and CINAHL (1982 to October 2005).

Selection criteria
Randomised controlled trials comparing electromagnetic therapy with sham electromagnetic therapy or other treatments.

Data collection and analysis
For the original review, details of eligible studies were extracted and summarised using a data extraction sheet. Attempts were made to obtain missing data by contacting authors. A second reviewer checked data extraction. Meta-analysis was applied to combine the results of trials where the interventions and outcome measures were adequately similar.

For this first update, two reviewers independently scrutinized the results of the search to identify relevant RCTs and obtained full reports of potentially eligible studies. In the case of disagreements, a final decision was made either after discussion between two reviewers or consultation with a third party (a member of the Cochrane Wounds Group).

Main results
This update identified no new trials. A total of three eligible RCTs were identified by the original review. Two trials compared the use of electromagnetic therapy with sham therapy and one trial compared it with standard topical treatments. One trial found a difference in healing rates of borderline statistical significance between electromagnetic therapy and sham therapy, although the direction of treatment effect was consistently in favour of electromagnetic therapy, the difference was not statistically significant.
Authors’ conclusions

There is currently no reliable evidence of benefit of electromagnetic therapy in the healing of venous leg ulcers. Further research is needed.

**Plain Language Summary**

Electromagnetic therapy for treating venous leg ulcers

Venous leg ulcers (which appear as open sores) can be caused by a blockage or breakdown in the veins of the legs. Compression, using bandages or hosiery (stockings), can help heal most of these ulcers. Electromagnetic therapy is also sometimes offered. Electromagnetic therapy is not a form of radiation or heating, but uses a field of electricity to try to promote healing. This review of trials concluded that, at present, there is no reliable evidence to show whether electromagnetic therapy can help heal venous leg ulcers.

**Background**

A leg ulcer is a common, chronic, recurring condition defined as the "loss of skin below the knee on the leg or foot, which takes more than six weeks to heal" (NHS CRD 1997). Within the UK population, the estimated prevalence of leg ulcers is 1.5 to 3 per 1000. However, prevalence increases with age, mounting to 20 per 1000 in people over 80 years old (NHS CRD 1997), and is higher among women (Callam 1986). Callam 1986 reports that 45% of people in a Scottish study experienced episodes of ulceration for more than 10 years. Leg ulcers constitute a considerable cost to both the patient (Charles 1995), and the health service (Bosanquet 1992). Indeed, the economic cost of leg ulcers to the NHS has been estimated at £400 million a year (Simon 2004). Venous ulcers (also known as stasis, or varicose ulcers) cause 80 to 85% of all leg ulcers (Simon 2004). They are caused by venous insufficiency, which has been shown to be associated with increased hydrostatic pressure in the veins of the leg. The application of external compression reverses this, and generally leads to the healing of venous leg ulcers (Cullum 2001).

However, a significant proportion of ulcers do not heal with compression therapy, and additional treatments are used for this group of people. Electrical stimulation has been used for decades as a treatment for chronic wounds (Hewitt 1956), and is often applied by physical therapists. However, its role in promoting venous leg ulcer healing, as an adjunct to, or in the absence of other proven therapies, is unclear.

The role of electricity in wound healing has been a topic for research since, at least, the 1940s (Burr 1940). Experimental animal studies have shown that electric potential over a wound during healing is positive initially, but becomes negative after the fourth day of healing (Weiss 1990). It has been concluded that the proliferative phase of healing is related to a negative electric potential over the wound. However, some studies have experimented with positive wound electrodes, and others have reversed the electrodes during healing. It is hypothesised that electrical stimulation influences the migratory, proliferative and synthetic functions of fibroblasts, and also results in increased expression of growth factors (Weiss 1990). It seems likely that a moist wound environment is essential to maintain the flow of an endogenous or applied current.

Electromagnetic therapy is distinct from most other forms of electrotherapy in that it is a field effect and not a direct electrical effect or a form of radiation (Stiller 1992). The wide spectrum of the electromagnetic band includes many radiations such as radio waves. The frequency of short-wavelength radio waves ranges from 10 to 100 MHz. Short Wave Diathermy (SWD) is one non-ionising form of radiation from the radio waves portion of the electromagnetic spectrum. The form of SWD that is used therapeutically employs the wave band of 27.12 MHz. SWD can be applied continuously, though some SWD machines apply the electromagnetic energy to people in short bursts of energy called pulsed short wave diathermy (PSWD). The interrupted, or pulsed, nature of PSWD is the only way in which it differs from continuous SWD, and these pulses create side bands (26.95 to 27.28 MHz). So, when PSWD is applied, no SWD is delivered at that time. PSWD delivers a lower dose of SWD, and thus the tissues receive a correspondingly lower thermal load. Consequently, PSWD provides the tissues with an energy boost in the form of an electromagnetic field (Kitchen 2002). PSWD is often termed pulsed electromagnetic field (PEMF) to distinguish it from SWD.

**Objectives**

Electromagnetic therapy for treating venous leg ulcers (Review)

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The aim of this review was to assess systematically the evidence for the effectiveness of electromagnetic therapy in the treatment of venous leg ulcers.

We sought to answer the following questions:

1. Does electromagnetic therapy stimulate venous leg ulcer healing?
2. If it does, what is the optimum treatment regimen, in terms of polarity, waveform, current density, duration and frequency of treatments?

M E T H O D S

Criteria for considering studies for this review

Types of studies
Randomised controlled trials (RCTs), and trials where the allocation of people to alternative therapies was described as 'randomised' were eligible for inclusion. There was no restriction on the basis of language, date of trial or publication status.

Types of participants
Studies that involved people of any age, and in any care setting, described as having a 'venous leg ulcer' were eligible for inclusion. As the method of diagnosis of venous ulceration differed between the trials, and was not always described, it was not possible to apply a standard definition.

Types of interventions
Any form of electromagnetic therapy for healing of venous ulcers compared with sham electromagnetic therapy, no electromagnetic therapy or other treatments.

Types of outcome measures

Primary outcomes
Objective measures of healing such as:
- time to complete healing;
- proportion of ulcers healed within trial period;
- rate of change in ulcer area

Secondary outcomes
- costs;
- quality of life;
- pain;
- acceptability of treatment

Search methods for identification of studies

Electronic searches
For this first update of the review, a new search using a new search strategy was carried out in the Cochrane Wounds Group Specialised Register (last searched in October 2005); the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2005, Issue 4); MEDLINE (1966 to October 2005); EMBASE (1980 to October 2005); and CINAHL (1982 to October 2005), to find randomised controlled trials (RCTs) of electromagnetic therapy. There was no restriction on the basis of language, date of trial or publication status.

Search strategy for searching the Cochrane Library (CENTRAL):
1. LEG ULCER explode all trees (MeSH)
2. VARICOSE ULCER explode all trees (MeSH)
3. WOUND HEALING explode all trees (MeSH)
4. (leg near ulcer*)
5. (varicose near ulcer*)
6. (venous near ulcer*)
7. (chronic near skin near ulcer*)
8. (stasis near ulcer*)
9. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
10. ELECTRIC STIMULATION THERAPY explode all trees (MeSH)
11. ELECTROMAGNETICS explode all trees (MeSH)
12. electromagnetic*
13. (electric* near stimulation*)
14. (electric* near therapy)
15. (pulse* near therapy)
16. (pulsed or Diapulse*)
17. DIATHERMY explode all trees (MeSH)
18. electrotherapy
19. MICROWAVES explode all trees (MeSH)
20. #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
21. (#9 and #20)
The search strategy for searching MEDLINE, EMBASE, CINAHL (Ovid online) is available in Appendix 1.

Searching other resources

Experts (e.g. Joyce E Kenkre), and manufacturers (Diapulse and Elmedistraal), in the field were also contacted in March 2005 and
Data collection and analysis

Selection of studies

For the original review, one author (KF) assessed the eligibility of titles and abstracts of studies identified by the search of the Wounds Group Specialised Register. Full reports of articles were obtained if, from this initial assessment, they appeared to satisfy the inclusion criteria. Another author (NC) checked those rejected. Full papers were checked to identify those that were eligible for inclusion (KF). Another author (NC) repeated this independently to provide verification. Any disagreement was resolved by discussion and, if necessary, was referred to a third party for adjudication.

For this first update, two authors (AOM and HR) independently checked titles and abstracts of studies identified by the update search for eligibility. Full reports of articles were obtained if, from this initial assessment, they appeared to satisfy the inclusion criteria. Full papers were checked by two authors independently to identify those that were eligible for inclusion. Any disagreement was resolved by discussion and, if necessary, was referred to a third party (from the Cochrane Wounds Group) for adjudication. Details of the eligible studies were extracted and summarised using a data extraction sheet. Attempts were made to obtain any missing data by contacting the study authors.

Data extraction and management

Data from studies published in duplicate were included only once. Data extraction was undertaken by one author and checked for accuracy by a second. The following data were extracted:

1. design of study;
2. inclusion and exclusion criteria;
3. baseline characteristics (by treatment group);
4. intervention details;
5. outcome measures used;
6. results (by treatment group);
7. withdrawals (by treatment group).

Assessment of risk of bias in included studies

Each study was appraised using a standardised checklist to assess the validity of the methods used. The following data relating to study quality were collected:

1. evidence that a sample size calculation was applied before trial commencement;
2. use of clear inclusion and exclusion criteria;
3. allocation concealment (A, B, C);
4. reporting of baseline comparability of treatment groups for important variables;
5. use of intention to treat analysis;
6. extent of loss to follow up;
7. blinded outcome assessment.

Data synthesis

The studies included in the review were combined by narrative overview with a quantitative summary of the result of similar trials where appropriate. For each trial with important dichotomous outcomes, e.g. ulcers healed? (yes or no) a relative risk of healing with 95% confidence intervals was calculated. Where outcomes for continuous variables were presented as medians without confidence intervals, standard deviations, or some measure of the precision of the result, the median was entered into the analysis table and the data were not used in data synthesis.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

No new studies were identified in the update search. One study (Todd 1991) was excluded because the study design was a controlled clinical trial (CCT).

Three previously identified studies of electromagnetic therapy were included in the review (Ieran 1990; Stiller 1992; Kenkre 1996). Two studies compared the use of electromagnetic therapy to sham electromagnetic therapy (Ieran 1990; Kenkre 1996), while the third compared it with standard topical treatments (Stiller 1992).

The studies all contained small numbers of people, and sample sizes ranged from 19 to 44. All people were considered to have venous leg ulcers, although none of the papers reported how the diagnosis was reached.

Ieran 1990 recruited 44 people with venous leg ulcers to a double-blind RCT conducted in Italy. People were randomised to receive either electromagnetic therapy (75 Hz, 2.7 mT, with an impulse width 1.3 ms) (n = 22) for four hours per day, or sham stimulation (n = 22) for the same period of time. Patients carried out the stimulation at home. No compression therapy was administered. Oral and local antibiotic therapy was given concomitantly to both groups. The study ran over a three-month period. The outcome measured was the percentage of ulcers healed at three months.

Stiller 1992 randomised 31 people into a multi-centre, double-blind, sham-controlled trial in the USA. People were randomised to receive either electromagnetic therapy (75 Hz, 2.7 mT, with an impulse width 1.3 ms) (n = 22) for four hours per day, or sham stimulation (n = 22) for the same period of time. Patients carried out the stimulation at home. No compression therapy was administered. Oral and local antibiotic therapy was given concomitantly to both groups. The study ran over a three-month period. The outcome measured was the percentage of ulcers healed at three months.

Stiller 1992 randomised 31 people into a multi-centre, double-blind, sham-controlled trial in the USA. Eighteen people randomised to the active treatment group received pulsed electromagnetic therapy (0.06 mV/cm, with a signal which is a three-
part pulse (+, -, +) of 3.5 ms total width and a duty cycle of 25%), delivered by a Pulsed Electromagnetic Limb Ulcer Therapy (PELUT) device for three hours a day plus standard treatment. Thirteen people were randomised to receive sham-electromagnetic therapy and standard treatment. The groups were treated over an eight-week period, or until the ulcer healed, whichever came first. Treatment continued to 12 weeks for patients that showed a favourable response at eight weeks. A computer-generated code was used to randomise the people. Standard treatment consisted of compression bandaging, leg elevation, and the use of one of five named dressings. Three outcomes were measured: percentage change in wound area; mean decrease in wound depth; and percentage change in area of granulation tissue.

The Kenkre 1996 study examined the treatment of venous leg ulcers with electromagnetic therapy in a randomised, controlled, double-blind trial based in a leg ulcer clinic in an urban general practice in Birmingham, UK. Nineteen people were randomly allocated into three arms: the first treatment group received 600 Hz electric field, and 25 mTesla magnetic field, delivered by an Elmedistraal device (which generates perpendicular electric and magnetic fields). The second group received 600 Hz on days one to five, and 800 Hz on days six to 30 from a 25 mTesla magnetic field, delivered by an Elmedistraal device, for 30 minutes, five days a week for a total of 30 days followed by four weeks’ observation. The control group received sham therapy. All people had ulcer dressings changed by community staff, although there was no standardisation of dressings. All patients were reported to be receiving compression therapy, the authors reported that only two people received ‘adequate’ compression. The objective outcome was the percentage of ulcers healed.

**Risk of bias in included studies**

All three trials reported their methods of randomisation and all studies reported allocation concealment. Two studies (Ieran 1990; Stiller 1992) reported drop-outs but one (Ieran, 1990) did not undertake an intention to treat (ITT) analysis. Stiller 1992 undertook ITT analysis for only one outcome (wound area). For further details of the methodological quality of included studies see Table 1.

**Effects of interventions**

The results are reported with reference to the original questions posed by the review.

**Does treatment with electromagnetic therapy enhance leg ulcer healing?**

Two trials compared the use of electromagnetic therapy with sham therapy (Ieran 1990; Kenkre 1996), and one trial (Stiller 1992) compared it with standard topical treatments. Ieran 1990: Three people in the control group (14%) and four in the experimental one (18%) were lost to follow up and thus excluded from the analysis. Therefore, 19 people in the control group and 18 in the experimental group were included in the analysis. In the electromagnetic therapy group at 90 days, twelve out of 18 (67%) ulcers had healed, compared with six out of 19 (32%) in the sham therapy group: the relative risk (RR) was 2.11 (95% confidence interval (CI) 1.01 to 4.42)(Analysis 1.1). However, the control group ulcers were larger at baseline (thus biasing the trial in favour of the electromagnetic therapy group). Moreover, if the people lost to follow up were regarded as treatment failures, the difference would not be statistically significant: RR 2.0 (95% CI 0.92 to 4.37). Kenkre 1996: At 50 days, when the two electrotherapy treatment arms were grouped together, two out of 10 (20%) venous ulcers were healed in the electromagnetic therapy group, compared with two out of nine (22%) in the sham electromagnetic therapy group: the RR was 0.90 (95% CI 0.16 to 5.13)(Analysis 1.2) after a 50 day period. Stiller 1992 (Analysis 2.1): The ulcers in the electrotherapy group had decreased in size by 47% by eight weeks, whilst in the control group the ulcers increased in size by 49% over the same time period (P value less than 0.0002, ANOVA). For people who discontinued the study prior to day 42, the wound area at eight weeks was determined by two methods: either estimated by linear extrapolation to day 56, or by use of the last observed wound area in place of the eight-week value. The results based on the last observed values were similar to those based on the extrapolated eight-week values. The treatment group averaged a 48% decrease in wound surface area compared to a 42% increase seen in the placebo group (P value less than 0.0002). The ulcers were matched at baseline for size. There was no statistically significant difference in baseline ulcer size between the sham therapy and electromagnetic therapy group (7.66 ± 1.62 cm² versus 7.25 ± 1.02 cm² respectively). The studies by Ieran 1990 and Kenkre 1996 were not pooled due to the variations in treatment period in the two studies.

**DISCUSSION**

There is no reliable evidence of an effect of electromagnetic therapy on the healing of venous leg ulcers. However, only three very small trials have been undertaken, none of which had sufficient statistical power to detect any statistically significant clinical differences. Furthermore, the one trial (Ieran 1990) that found a borderline statistical significance in favour of electromagnetic therapy was biased in favour of electromagnetic therapy, as baseline measurements showed that the control group ulcers were larger than
those in the treatment group at the start of the trial. It is worth noting that the healing rates in the control groups of all the studies in particular those of Ieran 1990 and Stiller 1992 were poor. Expected healing rates after a 12-week period of compression would be 50% (Cullum 2001), rather than 32% described in the Ieran 1990 trial, and the increase in ulcer size observed in the Stiller 1992 trial. Together, the three trials do not provide sufficient reliable information about the effects of electromagnetic therapy on venous ulcers, and further research is required.

**AUTHORS’ CONCLUSIONS**

**Implications for practice**

At present, there is insufficient evidence from RCTs to support the routine use of electromagnetic therapy in practice.

**Implications for research**

The three studies summarised in this review are underpowered and methodologically weak, and indicate that electromagnetic therapy requires further evaluation in larger, well-designed studies. Future trials will require:

1. clearly defined inclusion and exclusion criteria for participants;
2. sample size with sufficient power to detect true treatment effects;
3. use of true randomisation with allocation concealment (e.g. remote randomisation centres, computer generated codes);
4. measures to help ensure comparability of treatments at baseline (e.g. stratification for ulcer size);
5. blinded outcome assessment;
6. use of objective outcome measurement (e.g. ulcer area, complete healing rates); and
7. use of an intention-to-treat protocol.

Future studies should explore the effects of electromagnetic therapy as an adjunct to optimum treatment with compression, and also as an option for people who cannot tolerate compression or for whom compression is contraindicated. In addition, the procedures for diagnosing venous leg ulcers, and the stage of the wound(s) should be described.

Randomised controlled trials should be adequately reported. The CONSORT statement (Begg 1996) lists 21 items that need to be reported to show readers whether or not a trial is likely to produce valid and reliable results. Further research into the relationship of electromagnetic therapy and the healing of venous leg ulcers needs to be reported in accordance with these guidelines.

**ACKNOWLEDGEMENTS**

The authors would like to thank Ali Baba Akbari Sari from the Cochrane Wounds Group for his comments on the development and update of the search strategy.

The authors would also like to thank Sally Bell-Syer and Wendy Milborrow from the Cochrane Wounds Group for their support and assistance on the update process.

**REFERENCES**

**References to studies included in this review**

**Ieran 1990 [published data only]**


**Kenkre 1996 [published data only]**


**Stiller 1992 [published data only]**


**References to studies excluded from this review**

**Todd 1991 [published data only]**


**Additional references**

**Begg 1996**


**Bosanquet 1992**

Burr 1940

Callam 1986

Charles 1995

Cullum 2001

Hewitt 1956

Kitchen 2002

NHS CRD 1997

Simon 2004

Weiss 1990

* Indicates the major publication for the study
### Characteristics of included studies

**Ieran 1990**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, computer generated schedule in blocks of four. Double-blind</th>
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</thead>
</table>
| Participants | 44 patients with venous ulcers of at least 3 months duration  
  Baseline data  
  Mean duration of ulcer  
  A: 30 months (range 3-360 months)  
  B: 23 months (3-240 months).  
  Ulcers >15 cm² (n, mean, SD)  
  A: 4 (34.2 ± 15.5)  
  B: 7 (39.9 ± 23.9)  
  Ulcers < 15 cm² (n, mean, SD)  
  A: 14 (4.8 ± 2.9)  
  B: 12 (5.0 ± 3.3) |
| Interventions | A: (n=22) Stimulation of ulcer with single pulse electric current generating a magnetic field of 2.8 mT, frequency 75 Hz, impulse width 1.3 ms 3-4 hours daily for maximum of 90 days, or until ulcer healed  
  B: (n=22) Sham electric current therapy, same frequency and duration of treatment as Group A above. Patients did not receive compression therapy during the study |
| Outcomes | Healing at 90 days  
  A: 12/18 (67%)  
  B: 6/19 (32%)  
  P value<0.02.  
  Healing at 90 days including withdrawals as treatment failures:  
  A: 12/22 (55%)  
  B: 6/22 (27%). |
| Notes | Stopped use of simulator by 3 weeks  
  A: 1  
  B: 2  
  Patient used stimulation discontinuously:  
  A: 1  
  B: 1  
  Allergic reaction to drugs:  
  A: 1  
  B: 0  
  Developed rheumatoid arthritis:  
  A: 1  
  B: 0 |

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
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</table>
Kenkre 1996

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<th>Methods</th>
<th>RCT, allocation by pre-determined codes. Pilot study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>19 patients with venous leg ulcer, with unsatisfactory healing in last 4 weeks</td>
</tr>
<tr>
<td>Baseline data:</td>
<td>Mean duration of ulcer:</td>
</tr>
<tr>
<td></td>
<td>A: 230.4 weeks (range 36-728 weeks)</td>
</tr>
<tr>
<td></td>
<td>B: 418 weeks (36-1368 weeks)</td>
</tr>
<tr>
<td></td>
<td>C: 962.6 weeks (160-2548 weeks).</td>
</tr>
<tr>
<td>Mean length of ulcer:</td>
<td></td>
</tr>
<tr>
<td>A: 26.6 mm (range 11-75 mm)</td>
<td></td>
</tr>
<tr>
<td>B: 49 mm (35-74 mm)</td>
<td></td>
</tr>
<tr>
<td>C: 49.1 mm (26-115 mm).</td>
<td></td>
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<tr>
<td>Mean ulcer area:</td>
<td></td>
</tr>
<tr>
<td>A: 63 mg (range 6-269 mg)</td>
<td></td>
</tr>
<tr>
<td>B: 81 mg (46-197 mg)</td>
<td></td>
</tr>
<tr>
<td>C: 119 mg (35-526 mg).</td>
<td></td>
</tr>
<tr>
<td>Patients with repeated ulceration:</td>
<td></td>
</tr>
<tr>
<td>A: 4</td>
<td></td>
</tr>
<tr>
<td>B: 3</td>
<td></td>
</tr>
<tr>
<td>C: 8.</td>
<td></td>
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</tbody>
</table>

| Interventions       | A: (n=5) 600 Hz electric field, 25 mT magnetic field, delivered by Elmedistraal. |
|                    | B: (n=5) 600 Hz on days 1-5, 800 Hz on days 6-30, 25 mT magnetic field, delivered by Elmedistraal, 30 mins treatment, 5 days a week for 30 days followed by 4 weeks' observation. |
|                    | C: (n=9) Sham therapy. |
|                    | All patients had ulcer dressings changed by community staff. No standardisation of dressings. All patients reported to be receiving compression therapy - authors report only 2 patients received ‘adequate’ compression |

| Outcomes            | No. of ulcers healed at day 50: |
|                     | A: 1 |
|                     | B: 1 |
|                     | C: 2. |

| Notes               | All patients had ulcer dressings changed by community staff. No standardisation of dressings. All patients reported to be receiving compression therapy - authors report only 2 patients received ‘adequate’ compression |

### Risk of bias

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<th>Item</th>
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<td>Allocation concealment?</td>
<td>Yes</td>
<td>A - Adequate</td>
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### Stiller 1992

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT, computer generated randomisation based on order of admittance to study</th>
</tr>
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</table>
| Participants | Venous leg ulcer greater than 7.0 cm diameter; no response to non-surgical treatment in 4 weeks prior to study; ulcer stability (greater than 15% change in diameter, greater than 15% change in percentage of granulation tissue in 2 weeks prior to study)  
Baseline data  
Mean ulcer duration:
A: 38.9 weeks (SD ± 5.2 weeks)  
B: 46.8 weeks (SD ± 11.3 weeks)  
Mean ulcer area:
A: 7.25 cm² (SD ± 1.02 cm²)  
B: 7.66 cm² (SD ± 1.62 cm²)  
Mean ulcer depth:
A: 0.24 cm (SD ± 0.04cm)  
B: 0.26 cm (SD ± 0.01cm).  
Each subject had one designated study ulcer. |
| Interventions | A: (n=18) pulsed electromagnetic limb ulcer therapy (PELUT)Signal - 3 part pulse 3.5 ms total width and duty cycle of 25%, 0.06 mV/cm, polarity (+, -, +), 3 hours daily for 8 weeks or until the ulcer healed, plus: ancillary topical treatment as below.  
B: (n=13) Ancillary topical treatment. Ace compression bandage (20 mmHg at ankle level) + leg elevation + dressing |
| Outcomes | Percentage change in ulcer size at 8 weeks  
A: 47% decrease  
B: 49% increase  
P value<0.0002 (ANOVA).  
Intention to treat analysis (discontinuing study pre 42 weeks)  
A: 48% decrease,  
B: 42% increase,  
P value<0.0002. |
| Notes | Withdrawals  
A: 1  
B: 3  
Reasons not given by group. |

### Risk of bias

<table>
<thead>
<tr>
<th>Item</th>
<th>Authors’ judgement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment?</td>
<td>Yes</td>
<td>A - Adequate</td>
</tr>
</tbody>
</table>

mg = milligram  
h = hour(s)  
Hz = Hertz (Unit of frequency)  
mins = minutes  
ms = millisecond
Characteristics of excluded studies  [ordered by study ID]

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Todd 1991</td>
<td>In the initial assessment, the title and abstract of this study seemed relevant to the objective of the review. It was excluded because searching the full paper revealed that the study to be a controlled clinical trial (CCT) and not a randomised controlled trial (RCT)</td>
</tr>
</tbody>
</table>
### DATA AND ANALYSES

#### Comparison 1. Electromagnetic therapy versus sham electromagnetic therapy

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Ulcers healed at 90 days</td>
<td>1</td>
<td>37</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>2.11 [1.01, 4.42]</td>
</tr>
<tr>
<td>2 Ulcers healed at 50 days</td>
<td>1</td>
<td>19</td>
<td>Risk Ratio (M-H, Random, 95% CI)</td>
<td>0.9 [0.16, 5.13]</td>
</tr>
</tbody>
</table>

#### Comparison 2. Electromagnetic therapy versus standard therapy

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Percentage change in ulcer size at 8 weeks</td>
<td>1</td>
<td>31</td>
<td>Std. Mean Difference (IV, Fixed, 95% CI)</td>
<td>Not estimable</td>
</tr>
</tbody>
</table>

#### Analysis 1.1. Comparison 1 Electromagnetic therapy versus sham electromagnetic therapy, Outcome 1 Ulcers healed at 90 days.

**Review:** Electromagnetic therapy for treating venous leg ulcers

**Comparison:** 1 Electromagnetic therapy versus sham therapy

**Outcome:** 1 Ulcers healed at 90 days (complete case analysis)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>EMT n/N</th>
<th>Sham-EMT n/N</th>
<th>Risk Ratio M-H Fixed, 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ieran 1990</td>
<td>12/18</td>
<td>6/19</td>
<td>2.11 [1.01, 4.42]</td>
<td>100.0%</td>
<td>2.11 [1.01, 4.42]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>18</strong></td>
<td><strong>19</strong></td>
<td></td>
<td><strong>100.0%</strong></td>
<td><strong>2.11 [1.01, 4.42]</strong></td>
</tr>
</tbody>
</table>

Total events: 12 (EMT), 6 (Sham-EMT)

Heterogeneity: not applicable

Test for overall effect: Z = 1.98 (P = 0.047)

Test for subgroup differences: Not applicable
## Analysis 1.2. Comparison 1 Electromagnetic therapy versus sham electromagnetic therapy, Outcome 2 Ulcers healed at 50 days.

**Review:** Electromagnetic therapy for treating venous leg ulcers

**Comparison:** 1 Electromagnetic therapy versus sham electromagnetic therapy

**Outcome:** 2 Ulcers healed at 50 days

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Sham</th>
<th>EM therapy</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Random,95% CI</td>
<td></td>
<td>M-H,Random,95% CI</td>
</tr>
<tr>
<td>Kenkre 1996</td>
<td>2/10</td>
<td>2/9</td>
<td>1.00</td>
<td>100.0%</td>
<td>0.90 [0.16, 5.13]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>10</strong></td>
<td><strong>9</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>0.90 [0.16, 5.13]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 2 (Sham), 2 (EM therapy)
Heterogeneity: not applicable
Test for overall effect: Z = 0.12 (P = 0.91)

## Analysis 2.1. Comparison 2 Electromagnetic therapy versus standard therapy, Outcome 1 Percentage change in ulcer size at 8 weeks.

**Review:** Electromagnetic therapy for treating venous leg ulcers

**Comparison:** 2 Electromagnetic therapy versus sham therapy

**Outcome:** 1 Ulcers healed at 90 days (per ITT analysis: withdrawals considered as ulcers not healed)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>EMT</th>
<th>Sham-EMT</th>
<th>Risk Ratio</th>
<th>Weight</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>M-H,Fixed,95% CI</td>
<td></td>
<td>M-H,Fixed,95% CI</td>
</tr>
<tr>
<td>Ieran 1990</td>
<td>12/22</td>
<td>6/22</td>
<td>2.00 [0.92, 4.37]</td>
<td>100.0%</td>
<td>2.00 [0.92, 4.37]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>22</strong></td>
<td><strong>22</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>2.00 [0.92, 4.37]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 12 (EMT), 6 (Sham-EMT)
Heterogeneity: not applicable
Test for overall effect: Z = 1.74 (P = 0.082)
Test for subgroup differences: Not applicable
### ADDITIONAL TABLES

Table 1. Methodological quality of included studies

<table>
<thead>
<tr>
<th>Trial identifier</th>
<th>Pts in trial/arms</th>
<th>Incl/excl criteria</th>
<th>Sample size calc</th>
<th>Randomisation</th>
<th>Allocation</th>
<th>Baseline features</th>
<th>Blinded</th>
<th>Outcomes</th>
<th>ITT analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ieran 1990</td>
<td>44/2</td>
<td>listed</td>
<td>no</td>
<td>computer generated schedule in blocks of four</td>
<td>yes</td>
<td>reported, larger ulcers in the control group</td>
<td>yes</td>
<td>appropriate</td>
<td>no</td>
</tr>
<tr>
<td>Stiller 1992</td>
<td>31/2</td>
<td>listed</td>
<td>no</td>
<td>computer generated</td>
<td>yes</td>
<td>reported</td>
<td>yes</td>
<td>appropriate</td>
<td>yes (only for an outcome)</td>
</tr>
<tr>
<td>Kenkre 1996</td>
<td>19/3</td>
<td>listed</td>
<td>no</td>
<td>allocation by pre-determined codes</td>
<td>yes</td>
<td>reported - control group ulcers were larger and of a longer duration</td>
<td>no</td>
<td>insufficient follow up to see complete healing</td>
<td>no</td>
</tr>
</tbody>
</table>

### APPENDICES

Appendix 1. Ovid MEDLINE, EMBASE & CINAHL search strategy

Search strategy for searching MEDLINE, EMBASE, CINAHL (Ovid online):

1. LEG ULCER/
2. VARICOSE ULCER/
3. WOUND HEALING/
4. (leg adj3 ulcer$)
5. (varicose adj3 ulcer$)
6. (venous adj3 ulcer$)
7. (chronic adj3 skin adj3 ulcer$)
8. (stasis adj3 ulcer$)
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. ELECTRIC STIMULATION THERAPY/
11. ELECTROMAGNETICS/
12. electromagnetic$.mp.
13. (electric$ adj3 stimulation$).mp.
14. (electric$ adj3 therapy).mp.
15. (pulse$ adj3 therapy).mp.
16. (pulsed or Diapulse$).mp.
17. DIATHERMY/
18. electrotherapy.mp.
19. MICROWAVES/
20. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. randomised controlled trial.pt.
22. controlled clinical trial.pt.
23. randomised controlled trials.sh.
24. random allocation.sh.
25. double blind method.sh.
26. single blind method.sh.
27. 21 or 22 or 23 or 24 or 25 or 26
29. 27 not 28
30. clinical trial.pt.
31. CLINICAL TRIAL/
32. (clin$ adj25 trial$).ti,ab.
33. ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
34. placebos.sh.
35. placebo$.ti,ab.
36. random$.ti,ab.
37. research design.sh.
38. 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37
39. 38 not 28
40. 39 not 29
41. comparative study.sh.
42. EVALUATION STUDIES/
43. follow up studies.sh.
44. prospective studies.sh.
45. (control$ or prospectiv$ or volunteer$).ti,ab.
46. 41 or 42 or 43 or 44 or 45
47. 46 not 28
48. 47 not (29 or 40)
49. 29 or 40 or 48
50. 9 and 20
51. 49 and 50

**WHAT'S NEW**

Last assessed as up-to-date: 31 December 2005.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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<tbody>
<tr>
<td>7 August 2009</td>
<td>Amended</td>
<td>Contact details updated.</td>
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HISTORY

Review first published: Issue 1, 2001

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>5 September 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
</tr>
<tr>
<td>1 January 2006</td>
<td>New citation required but conclusions have not changed</td>
<td>Substantive amendment. For this first update, new searches were carried out in October 2005. No new studies were included. One study was excluded. The reviewers' conclusions remain unchanged</td>
</tr>
</tbody>
</table>

CONTRIBUTIONS OF AUTHORS

KF and NC conducted the original review.

HR ran the updated search and searched new databases to identify potentially relevant studies.

HR and AOM checked the studies independently for inclusion for this update.

HR drafted the update.

AOM provided comments on the update draft.

NC and KF commented on the final draft of the update.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- Department of Health Sciences, University of York, UK.
External sources

- NHS Health Technology Assessment Programme, UK.
- General Nursing Council of England and Wales Trust, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Electromagnetic Phenomena; Electric Stimulation Therapy; Randomized Controlled Trials as Topic; Varicose Ulcer [*radiotherapy]; Wound Healing

MeSH check words

Humans