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Results: Statistically significant reductions in ulcer measurement were noted in the treatment group when compared with the placebo group.
Conclusion: The results demonstrate a significant healing effect in the treatment group. A larger randomised controlled study is recommended to investigate the effects on ulcer-associated pain and quality of life.
Declaration of interest: The study was supported by Magnopulse, Bristol, UK.

"With the relatively few numbers of patients in the trial we were not expecting to observe such a clear difference due to the magnetic device ..... we felt that the results were of such potential importance that they merited publication at this stage. What is more significant is that these were all patients whose ulcers were failing to heal by other usual treatments."
Dr Nyjon Eccles (Lead Clinician for the study)

emap communications

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static magnetic device; wound healing

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Static magnets are thought to promote leg ulcer healing in a number of ways. This includes the promotion of injury current — injury current is generated at a wound site and is a crucial part of the healing mechanism.[1] Connective tissue cells placed in a static magnetic field increase proliferative and functional capacity by 20%.[2] They also increase circulation — increased blood perfusion and skin temperature have been observed,[3] as has pain relief.[4-6]

There is anecdotal evidence to support the effectiveness of static magnets in leg ulcer healing, but only one placebo-controlled trial was found to confirm this.[7] This double-blind placebo-controlled study of 20 patients undergoing suction lipectomy surgery of the abdomen and thighs examined postoperative wound progress with and without static magnets. In the magnet group, a statistically significant ($p<0.05$) reduction in pain, oedema ($p<0.05$) and discolouration ($p<0.05$) was reported. The authors commented that bruising would normally take two to three weeks to resolve, whereas with magnetic field therapy it resolved in 48–72 hours. This study scored 4 out of 5 on the Jadad methodological assessment scale.[8]

In 2003 a randomised telephone survey of 160 users of UlcerCare static magnet leg wraps set out to determine its effectiveness on healing and pain.[9] Average ulcer duration was 49 months and the device had been worn for an average of four months at the time of the survey. There were significant reductions ($p<0.0001$) in ulcer size (68%), swelling (71%) and pain, based on patients' reports using a visual analogue scale (VAS): 54.5% reported an improvement in ability to perform daily tasks and 64% reported an improvement in quality of life.[10]

The results of this survey were of such significance that they encouraged this randomised double-blind controlled pilot study.

Table 1. Group comparison of study participants

	No. in group	Sex (%) (male/female)	Age (mean [SD])	Ulcer aetiology		Withdrawal
Control	12	67/23 ADDS UP TO 90%	81 (8)	Mixed Venous Rheumatoid	25% 67% 8%	1 (death)
Intervention	16	75/25	79 (8)	Mixed Venous Rheumatoid	37.5% 62.5% 0%	2 (family issues, unable to tolerate compression)

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2 Bassett, C.A.L., Hermann, I. The effect of electrostatic fields on macromolecular synthesis by fibroblasts *in vitro*. J Cell Biol 1968; 39: 9a.

3 Mayrovitz, H.N., Larsen, P.B. Effects of pulsed electromagnetic fields on skin microvascular blood perfusion. Wounds 1992; 4: 197-202.

4 Gmitrov, J., Ohkubo, Ch., Okano, H. Effect of 0.25 T static magnetic field on microcirculation in rabbits. Bioelectromagnetics 2002; 23: 224-229.

Pain and functional status

There were no statistically significant differences in changes from baseline in any measure of pain status, daily activity, feelings, overall health, changes in health or quality of life at any time point (Table 4).

Discussion

Despite the small sample size, the significant trends demonstrated are considered grounds for further investigation to confirm results from previous studies.[1,9] Expert opinion suggests that patients who are receiving recommended treatment but are not healing should be reassessed at four weeks.[15] The inclusion criteria of a follow-up study could be changed to reflect this reassessment point and thus increase the number of patients eligible to be enrolled.

The only change in the normal care of study patients was the use of the magnetic leg wrap in the treatment group. Ethically, this was a strength of our study. Practitioners had to be able to continue providing evidence-based care for these patients. Any change in wound management and treatment of infection was based on best practice and was at the discretion of the nurses, so was not controlled.

To have used infection and any dressing change as exclusion criteria would have rendered the study so specific it would have been impossible to implement, given the recruitment difficulties. Although eight patients developed a critical colonisation/infection during the study, the infection rate appears to be consistent with professional experience of caring for patients with recalcitrant leg ulceration.

This is the first controlled trial to demonstrate a significant healing effect of an appropriately applied static magnetic field on chronic leg ulcers. Despite the small number of participants (26) and other problems encountered, the results are strongly in favour of significant healing in the treatment group. The results confirm those of other studies[9] that showed a significant reduction ($p<0.0001$) of 68% in ulcer size over an average of four months.

The absence of significant differences between the two groups in the changes from baseline in pain status, daily activity, feelings, overall health or quality of life at any time point may be due to the small number of subjects and the relative lack of significant pain as a symptom in the treatment group. In this study, nine out of 16 in the treatment group compared with two out of 12 in the placebo group rated their pain as 1 or 2 on a scale of 1 to 5. The survey[9] had shown a highly statistically significant ($p<0.0001$) reduction in leg pain and swelling in UlcerCare users but 160 subjects (76%) had significant associated leg pain. Clearly, a much larger controlled study is needed to examine the effect of static magnetic fields on those who may have had associated pain and swelling and to more fully establish a potential effect on quality of life and function.

Table 4. Pain and functional status measurements and statistical analyses

Pain	Placebo	Intervention	p-value
Baseline	3.5 (3.0, 4.8)	2.0 (2.0, 4.0)	
Change at week 4	0.0 (-1.0, 0.0)	0.0 (-1.0, 0.0)	0.72
Change at week 8	0.0 (-1.0, 0.0)	0.0 (-1.0, 0.0)	0.63
Change at week 12	-1.0 (-2.0, -1.0)	0.0 (-1.0, 0.3)	0.07
Activities			
Baseline	3.0 (2.0 ,3.8)	3.0 (2.0, 4.0)	
Change at week 4	0.0 (0.0, 0.0)	0.0 (-1.0, 0.0)	0.33
Change at week 8	0.0 (-0.8, 0.0)	0.0 (-1.0, 0.3)	0.93
Change at week 12	0.0 (-1.0, 0.0)	-0.5 (-1.3, 0.0)	0.59
Feelings			
Baseline	3.0 (1.0 ,3.0)	2.5 (2.0, 4.0)	
Change at week 4	0.0 (0.0, 0.0)	0.0 (-1.0, 0.0)	0.23
Change at week 8	0.0 (0.0, 0.0)	0.0 (-0.3, 0.0)	0.72
Change at week 12	0.0 (0.0, 0.0)	0.0 (-1.3, 1.0)	0.79
Overall health			
Baseline	3.0 (2.0 ,4.0)	3.0 (2.0 ,4.0)	
Change at week 4	0.0 (-1.0, 0.0)	0.0 (-1.0, 0.0)	0.89
Change at week 8	-0.5 (-1.0, 0.0)	0.0 (-1.3, 0.3)	0.50
Change at week 12	0.0 (-1.0, 1.0)	0.0 (-0.3, 1.0)	0.36
Quality of life			
Baseline	3.0 (2.0, 3.8)	3.0 (2.0, 3.0)	
Change at week 4	0.0 (-0.8, 0.0)	0.0 (0.0, 0.0)	0.79
Change at week 8	0.0 (-1.0, 0.0)	0.0 (-0.3, 0.0)	0.39
Change at week 12	0.0 (-1.0, 0.0)	0.0 (-1.0, 0.0)	0.44

All data are presented as median (IQR) and p-values refer to Mann-Whitney U test

Conclusion and recommendations

This study shows that an appropriately applied static magnetic device significantly promotes ulcer healing. Static magnets have also been shown to enhance wound healing.[7] Such a simple treatment modality warrants further attention, including a larger controlled study. The implications are far-reaching in terms of saving community and practice nursing time, as well as for the potential to reduce the significant NHS expenditure on chronic ulcer care. ■

Table 3. Ulcer size: statistical analyses — rates of change (units per week) for each treatment group (median [IQR])

Measure	Placebo	Intervention	p-value*
Ulcer area	0.0 (0.0, 0.4)	-0.1 (-0.2, 0.0)	0.04
Ulcer perimeter	0.1 (-0.1, 0.6)	-0.3 (-0.7, 0.1)	0.01
Ulcer length	0.0 (0.0, 0.1)	-0.1 (-0.2, 0.0)	0.02
Ulcer width	0.0 (0.0, 0.1)	-0.1 (-0.1, 0.0)	0.01
Ulcer hue	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.34

*Mann-Whitney U test

change per week at weeks four and 12 was calculated as follows: week 12 + week 4 ÷ 8. A negative value therefore indicates a reduction in ulcer size. These rates of change were also summarised using median (IQR) for each treatment group. The Mann-Whitney U test was used to compare them.

The data for pain and functional status are discrete (scores of 1–5). Baseline (week 0) values and changes from baseline at weeks four, eight and 12 were calculated using median (IQR) points for each treatment group. Differences in these changes between groups were evaluated using the Mann-Whitney U test. Unadjusted (for multiple comparisons [three time points]) p-values are reported. To give an overall significance level of 5% (per outcome measure), a p-value of less than 0.015 was considered statistically significant. To evaluate whether these outcomes changed significantly over time, a Friedman test was carried out for each group.

Missing data and drop-outs

Ulcer size measurements were missing because either the patient withdrew or died, or the measurements could not be taken from the photograph.

Of the 16 subjects in the treatment group, two withdrew, one of whom had measurements available at two time points so was included in the analysis, while the other had no measurements available, and so was excluded. Of the 14 treatment group subjects who completed the study, three had no measurements available, so were excluded from this part of the analysis. Thus, a rate of change in the measurements could be calculated for 12 patients.

Of the 12 subjects in the placebo group, one died, but as measurements were available at baseline, data from weeks four and eight were included in the analysis. One patient had measurements available at one time point only and was excluded as a rate of change could not be calculated. Therefore, in the placebo group a rate of change in the measurements was calculated for 11 patients.

Results

Twenty-eight patients with chronic leg ulcers took part in the study. Table 1 outlines group comparisons. The results of the withdrawn patients are included in the analysis.

We were very disappointed with the number of volunteers who enrolled. Difficulties encountered included:

- Gaining approval for access to patients in three different PCTs was a lengthy, convoluted process as different stakeholders needed to agree access to patients and practitioners, and there was no overarching research group that could be approached
- Supervising research/data collection involving multiple practitioners
- Issues around digital cameras/images used for data collection, such as incorrect placement of reference markers for photographs and incorrect picture angle for reliable analysis
- Limited number of patients enrolled in the study despite frequent support visits and phone calls to clinical areas. Practitioners' initial perception of suitable patients did not equate to the number who actually fitted the inclusion criteria.

Change in dressings

In both groups, four patients had their type of dressing changed during the study period after assessment. For example, one patient in the placebo group had their dressing changed from Promogran (Johnson & Johnson) to Aquacel (ConvaTec) after eight weeks as there was no improvement in the wound.

The category of dressing remained the same, apart from in two patients in the placebo group, where dressing changes related to a four-week period only due to the development of infection. There were no changes to the type or amount of compression used in either group.

Ulcer size

Data for ulcer area, perimeter, length and width are given in Table 2. Table 3 shows the rate of change (per week) for each type of measure. Patients with two or more ulcer-size measurements were included in the ulcer analysis to give as close to a full intention-to-treat analysis as possible. Rates of change were calculated for 23 subjects (12 treatment group).

The results in Table 3 indicate there was, on average, no change over time for these measures in the placebo group. Between-group differences in these rates of change were statistically significant for perimeter (p=0.01), length (p=0.02) and width (p=0.01). The difference in rate of change of area was marginally significant (p=0.04). Four patients in the treatment group who had data measurements at 12 weeks had no measurable ulcer at the end of this period. Of the placebo group, seven had data measurements at 12 weeks and still had measurable ulcers.

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Method

Our aim was to recruit 100 patients with non-healing chronic leg ulcers of multiple origin. A power calculation was performed, which assumed, based on clinical experience, that the percentage of healing following standard care for all ulcers combined is 40%. We assumed that the power of the trial to detect the required treatment difference would be 80% and that the level of significance for detecting this difference would be equal to 5%. Therefore, to detect a difference of 25% due to the treatment, 60 subjects would be required in each arm. To detect a difference of 30% would require 20 in each arm. On the basis of our survey data we were expecting differences of up to 60%. We felt that 100 subjects would give us the flexibility to detect smaller differences than anticipated. Exclusion criteria included cancer-related ulcers, diabetic foot ulcers and neuropathic ulcers.

All patients were receiving evidence-based care.[11] They were randomly allocated to receive a sham non-magnetic device (control) (n=12) or UlcerCare (intervention) (n=16). The difference in size in the two groups was a result of the randomisation process.

Both devices were identical in appearance. The UlcerCare is a self-securing leg wrap worn just below the knee, proximal to the calf. It contains four powerful neodymium magnets (2000 Gauss) with directional plates that allow the negative enhanced magnetic field to be absorbed deeper into the tissues.This is thought to give a superior and longer lasting effect.

Nurses were trained by a senior teaching practitioner how to apply the devices but neither they nor the patient were aware which device was being applied (this was only revealed after analysis of the results). Subjects were told this was a study of a metallic device as knowing a magnet is present often leads study participants to try to establish its nature using metallic objects.[12] Also, the local research ethics committee recommended that the patient information sheet should refer to a metallic device rather than a magnetic one. However, practitioners were informed of the nature of the device under test.

Both groups continued with conventional therapy — that is, dressings, wound care and compression therapy as appropriate.

Ulcer assessment by digital photography and measurement was undertaken once every four weeks by the nurses who regularly cared for the patients, and was supported by the nurse researcher.

Photographs and ulcer size were analysed using the Verge Videometer, which provided measurements of ulcer perimeter, area, maximum length, maximum width and hue. Identification and treatment of infection was noted and dated on each patient's log. Data were stored according to the Data Protection Act.[13]

Pain in the lower limb was logged using a VAS ranging from 1 (no pain) to 5 (severe pain).

A modified COOP measure of functional status chart[10] was used to assess daily activities, feelings, overall health, changes in health and quality of life. Each was graded on a scale of 1 to 5 at monthly intervals. Details of wound care, dressings and compression therapy applied were recorded.

The study endpoint was set at 12 weeks, taking into account previous ulcer studies.[11,14]

Ethical approval was sought and obtained from East Suffolk local research ethics committee.

Table 2. Ulcer measurements

	Placebo (n=12)		Intervention (n=16)	
Ulcer area				
0 (baseline)	5.2 (2.6, 12.6)	n=12	3.4 (1.4, 6.5)	n=10
4 weeks	4.2 (2.0, 12.9)	n=10	2.3 (1.0, 3.9)	n=9
8 weeks	8.0 (3.7, 11.6)	n=10	2.2 (0.7, 9.6)	n=9
12 weeks	5.4 (1.6, 8.8)	n=7	0.3 (0.0, 3.5)	n=11
Ulcer perimeter				
0 (baseline)	10.2 (6.2, 17.4)	n=12	8.6 (5.8, 11.1)	n=10
4 weeks	8.4 (5.6, 17.9)	n=10	6.9 (4.2, 8.9)	n=9
8 weeks	13.6 (8.6, 18.6)	n=9	5.7 (2.1, 12.5)	n=9
12 weeks	10.8 (5.9, 13.3)	n=7	2.4 (0.0, 7.1)	n=11
Ulcer length				
0 (baseline)	3.7 (2.2, 6.7)	n=12	2.8 (2.1, 4.4)	n=10
4 weeks	3.2 (2.0, 6.3)	n=10	2.7 (1.2, 3.8)	n=9
8 weeks	4.5 (3.3, 6.3)	n=10	2.4 (0.7, 4.9)	n=9
12 weeks	3.8 (1.9, 4.4)	n=7	0.8 (0.0, 2.7)	n=11
Ulcer width				
0 (baseline)	1.9 (1.3, 2.9)	n=12	1.7 (1.1, 2.1)	n=10
4 weeks	1.9 (1.5, 2.9)	n=10	1.4 (0.8, 2.0)	n=9
8 weeks	2.8 (1.5, 3.4)	n=10	0.9 (0.6, 2.5)	n=9
12 weeks	2.2 (1.5, 3.4)	n=7	0.6 (0.0, 1.8)	n=11

All data are median (IQR); n = number of patients at this time point

Statistical methods

All the data describing ulcer size were skewed with a number of outliers. The raw data for each measure at each time point were summarised using the median (interquartile range [IQR]). For each of the ulcer size measurements, an average rate of change per week was calculated by subtracting the measurements furthest apart in time and dividing by the number of weeks. For example, an average rate of

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Related Studies

Healing Leg Ulcers

A Survey to Determine the Effectiveness of *UlcerCare*® Static Magnets on Leg Ulcer Healing and Leg pain - Dr Nyjon.K.Eccles & Derek Price

A survey conducted of 160 randomly selected users of *Magnopulse UlcerCare* static magnet leg wraps. Average ulcer duration was 49 months i.e. just over 4 years. The device had been worn for an average of 4 months.

The key findings were as follows:

- A highly significant reduction ($p < 0.0001$) in ulcer size of 68% was achieved over the treatment period. Forty one percent (41%) of patients experienced complete ulcer healing and only 11% of patients had no effect on ulcer size. The average time to heal in those that had complete healing was 3.9 months.
- 72% of those with associated swelling had a reduction in swelling after wearing UlcerCare with an average reduction in swelling of 71%. This reduction in swelling was highly statistically significant, $p < 0.0001$.
- 84.5% had a reduction in associated leg pain with UlcerCare. This reduction in pain was highly statistically significant, $p < 0.0001$. There was a statistically significant reduction in painkiller consumption after using UlcerCare ($p< 0.030$), with 57% of patients no longer taking painkillers at all.
- The majority, 54.5% reported an improvement in ability to perform daily tasks and 64% reported an improvement in the quality of life. This was at least in part due to less pain, less restriction and greater mobility.

Swollen and Painful Legs

A Survey to Determine the Effectiveness of *LegCare*® Static Magnets on Leg pain and Swelling – Dr Nyjon.K.Eccles & Derek R. Price

A survey was conducted of 202 randomly selected users of *Magnopulse LegCare* static magnet leg wraps. The majority of the patients, 67%, using the LegCare used it for knee pain. Average duration of pain was 87.2 months with a range 1 to 600 months. Forty-five percent of respondents had associated leg swelling.

The key findings were as follows:

- 96% of respondents said there was a reduction in leg pain after wearing the device. There was an average of 73% reduction in leg pain after wearing the LegCare. This reduction in pain was highly statistically significant ($p<0.0001$).
- 85% of those who responded had a reduction in pain of at least 50%. Furthermore, 31% had no pain at all after wearing the device and 49% had a reduction in pain of 70% or more.
- The majority, 75%, had a noticeable reduction in pain within 14 days of wearing the LegCare. More than half (54%) of LegCare users required no further treatment for their leg pain.
- Of those who had swelling, 72 of the original 202, 73% reported a reduction in leg swelling after wearing the LegCare. The average reduction in leg swelling after wearing the LegCare was 71%. This reduction in leg swelling was highly statistically significant ($p < 0.0001$).
- 65% reported an improvement in quality of life after wearing LegCare of which 10% were much better.
- No respondent reported any worsening of health from wearing the device.